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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Transcript of evidence
for

12 January 1984

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1 ROYAL COMMISSION OF INQUIRY INTO CERTAIN
2 DEATHS AT THE HOSPITAL FOR SICK CHILDREN
3 AND RELATED MATTERS.

4 Hearing held on the 8th Floor,
5 180 Dundas Street West, Toronto,
6 Ontario, on Thursday, the 12th
7 day of January, 1984.

8 THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
9 THOMAS MILLAR - Administrator
10 MURRAY R. ELLIOT - Registrar

11 APPEARANCES:

12 P.S.A. LAMEK, Q.C.) Commission Counsel
13 L. CECCHETTO Counsel for the Attorney
14 General and Solicitor General
15 of Ontario (Crown Attorneys
and Coroner's Office)
16 I.J. ROLAND) Counsel for The Hospital
M. THOMSON) for Sick Children
R. BATTY)
17 D. YOUNG Counsel for The Metropolitan
18 Toronto Police
19 K. CHOWN Counsel for numerous Doctors
20 at The Hospital for Sick
Children
21 E. McINTYRE Counsel for the Registered
22 Nurses' Association of Ontario
23 and 35 Registered Nurses at
24 The Hospital for Sick Children

25 (Cont'd)



1 APPEARANCES (Cont'd) :

2 D. BROWN Counsel for Susan Nelles -
3 Nurse

4 E. FORSTER Counsel for Phyllis Trayner -
5 Nurse

6 J.A. OLAH Counsel for Janet Brownless -
7 R.N.A.

8 B. KNAZAN Counsel for Mrs. M. Christie -
9 R.N.A.

10 S. LABOW Counsel for Mr. & Mrs. Gosselin,
11 Mr. & Mrs. Gionas, Mr. & Mrs.
12 Inwood, Mr. & Mrs. Turner, Mr.
13 Mrs. Lutes, and Mr. & Mrs.
14 Murphy (parents of deceased
15 children)

16 F.J. SHANAHAN Counsel for Mr. & Mrs. Dominic
17 Lombardo (parents of deceased
18 child Stephanie Lombardo); and
19 Heather Dawson (mother of
20 deceased child Amber Dawson)

21 W.W. TOBIAS Counsel for Mr. & Mrs. Hines
22 (parents of deceased child
23 Jordan Hines)

24 J. SHINEHOFT Counsel for Lorie Pacsai and
25 Kevin Garnet (parents of
 deceased child Kevin Pacsai).



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DP.jc

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2 --- On commencing at 9:30 a.m.

3 THE COMMISSIONER: There was an
4 index to Dr. Moller's report which has been given to
5 us by Miss Fineberg. I guess we will put that with
6 Exhibit 314. There is also an index to Mr. Cimbura's
7 report. Did you do this too, Miss Fineberg? Are
you responsible for this one as well?

8 MS. FEINBERG: Yes, I am.

9 THE COMMISSIONER: How do we know
10 whether it is 95 A, B or C? Have you numbered all
11 the pages or what has happened?

12 MS. FEINBERG: What has happened is
13 that the reference to each report is indicated by
the child's name.

14 THE COMMISSIONER: I see there is
15 95A, B, C, all right, that is fine. That will go
16 with Exhibit 95, then.

17 Yes, Miss McIntyre?

18 MS. MCINTYRE: Thank you, Mr.
19 Commissioner.

DR. BERNARD L. MIRKIN, Resumed

CROSS-EXAMINATION BY MS. MCINTYRE:

Q. Dr. Mirkin, I would like to
ask you some questions about the Inwood baby.

23 A. I beg your pardon?

24

25



A.2

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2

Q. Inwood - I believe it is

3

No. 32. As I understood your evidence, you thought
that this death was attributable to either high
potassium levels or to digoxin intoxication?

4

A. I think probably the latter more
likely in view of the data that was accumulated. As
far as the potassium was concerned, we had on March 13
obtained from the chart data indicating that this
patient had a serum potassium of 7.3. As far as I
understand, there was no mention whether this was
a hemolyzed or non-hemolyzed blood specimen. In the
event it was a hemolyzed specimen that concentration
might have been spuriously elevated. The only
reason the potassium comes in is that with 7.3 one
might have seen the symptoms that were presented on
March 13 in this patient where the heart rate slowed.
A high serum potassium is associated or can correlate
with that.

18

19

20

21

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Q. I take it that the reason that -

going to the digoxin for a moment - the data that you
referred to is the post mortem digoxin level?

A. That is correct. I think that

conclusion was based on those findings to a large
extent.

Q. And as I understand it your



A.3

1

2 team rating this child as zero did not find any
3 clinical indicators of digoxin intoxication?

4

5 A. That is correct. I am
6 getting at your question now. We gave Kristin Inwood
7 a rating of zero based on the scoring here which was
8 based primarily on the data available in the chart
9 in that we had no evidence of a digitalis-induced
10 arrhythmia and the blood level in this patient we
11 felt was certainly consistent with a non-toxic
12 therapeutic level, that is the blood level on March
13 12th, which was 2.6. Correct?

14

15

16

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Q. Yes, that is the ante mortem
level.

A. Exactly.

Q. I take it in going through

the final events as indicated in the chart
there was nothing in that to lead you to believe that
there was digoxin intoxication?

A. No, we could find nothing to
explain the findings in this patient. Of course I
will remind you that on March 11 the patient was in
no apparent distress and was tolerating feedings very
well. As you know, that is an excellent sign of an
infant doing reasonably well. On March 12, one day
later, the patient began to present signs of



A. 4

1

2 congestive failure, and on March 13 the baby expired.

3 Now, if one wants to make a scenario
4 out of this, one could say that the events that were
5 described on March 12 were attributable to some
6 effect on the function and performance of the heart
7 that could have been induced by a drug or by some
exogenous material.

8

Q. Would that include digoxin?

9

A. It would include digoxin I
10 think, that is an excess of it. This patient
11 presented here in the chart on March 12 signs of
congestive failure. The one thing that would probably
12 mitigate a little bit against the digoxin theory on
13 March 12th - I have in my notes the fact that the
14 patient's heart rate increased. If the patient had
15 really received a very large dose of digoxin I would
16 have anticipated a decrease in the heart rate. Okay?

17

Q. Is there some other explanation
18 that you have other than the possibility of digoxin
intoxication that would explain that scenario?

19

A. Again, going back to the other
20 potential factor that constitutes real data in this
21 patient, the serum potassium being elevated - well,
22 the serum potassium on March 12 was 5. That is
23 normally not going to produce any of these symptoms and

24

25



A.5

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2 I don't know how else to explain that other than a
3 change in the status of the condition of this patient
4 and one would say, well, it was secondary to the
5 basic disease of the patient, without knowing if
6 any other exogenous agent might have been presented
to this child.

7

Q. In any event I take it that
8 your real concern with respect to the digoxin
9 intoxication comes from the post mortem levels that
10 were reported?

11

A. I think that is a correct
conclusion on your part.

12

Q. I would like to have you look
13 at those for a moment. They are in Exhibit 95, if
14 you have a copy of that exhibit. Before you do that,
15 I would just remind you that within 24 hours of this
16 child's death she had received administration of
17 digoxin. She had been prescribed a dose of .006
18 milligrams and in error she had received another
19 baby's dose of .02 milligrams. That was within 24
20 hours of her death. The post mortem results, page 7
21 of 95A, showed certain concentrations in the tissues.

22

A. If you can hold a moment, I
do not have - I have it here, thank you.

23

Q. I take it, Doctor, given the

24

25



A. 6

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2 fact that she had received digoxin shortly before
3 her death that the tissue levels : found there
4 are not surprising?

5 A. Well, the tissue levels - I
6 think rather than say the tissue levels we should
7 probably say, I would, that the presence of digoxin
is not surprising.

8

Q. In the tissues?

9

A. Yes.

10

11 Q. I take it that you feel that
the actual level as opposed to the existence of
12 digoxin in tissues is hard to interpret?

13

A. I think under these circum-
stances it is, yes.

14

15 Q. So those levels then are not
the real concern? It is a level 491 that was found,
16 reported in Exhibit 95C, that is the real problem?

17

A. I believe so.

18

19

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Q. Doctor, have you been advised
as to the history of that particular sample?

4

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A. Yes. My understanding was --
or perhaps you want to refresh my memory on it.

6

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Q. Okay. As I understand it
this sample was taken for another purpose and it was
in the Virology Lab and had been in a vial in the
refrigerator in the Virology Lab for approximately
ten months. In fact, the history of the vial appears
to be relatively obscure and it is not clear whether
or not the vial was stoppered the entire time; it is
not clear whether it was frozen, heated, or what
conditions it went through. My question to you is
whether in your opinion that history might affect the
reliability of the measurement?

A. Well, certainly freezing
will not, in my department we freeze samples all the
time. Heating, to the extent that the sample is
allowed to reach room temperature, certainly does not
seem to be injurious or destroy the digoxin.
Boiling, on the other hand, for a projected period
might. But then I think the serum sample would have
obviously different characteristics that might have
been recognized by the lab; that is, you might look
at the inscription whether or not a protein had



1

2 been precipitated in the serum sample. That would
3 give you some sense of whether anything had occurred
4 to the sample to allow, how shall I say, a very
5 strenuous modification in its environment. I am
6 talking more about heat, heat labile material.

7

Q. What about the possibility of
evaporation?

8

A. No.

9

Q. If we have this liquid
10 substance sitting and it is not completely stoppered
11 if it has something over the top.

12

A. It was not frozen, I under-
stand, it was in the refrigerator , correct?

13

Q. Yes.

14

A. At about 4 degrees centigrade,
15 roughly.

16

Q. That is not entirely clear,
but that would seem to be most reasonable.

17

A. All right, if it was
refrigerated for a long time it really doesn't
evaporate too much and you can leave the stopper off.
Now, I think in all honesty -- one of the reasons I
don't think evaporation would occur here to a great
extent, though some might have occurred certainly,
is that the humidity in the refrigerator is probably

24

25



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2 such a level that perhaps not too much evaporation
3 will occur in that environment.

4 Q. Is there something unusual
5 about refrigerators in the laboratory that would
6 result in that? I know certainly things evaporate in
7 my refrigerator when I leave them sit.

8 A. Well, we do have an expert
9 here on culinary arts that we can bring into this
10 if we need. Depending on the refrigerator; as a
11 matter of fact, some of the units that are in
12 laboratories do have humidity control, and I presume
13 this is so. In a virology laboratory, however, it
14 might have been in a temperature controlled environ-
15 ment and I think it might be simple to inquire
16 if it were an ordinary refrigerator and so be it.
17 I think one would have to say, yes, the possibility
18 does exist that some evaporation might have occurred.
19 I think it is low likelihood and if evaporation oc-
20 curred this is possible that it might have increased
21 the relative concentration that was perceived by
22 assay.

23 Q. You say possibly, would it
24 not be in fact the case that if the volume were
25 reduced by 50% that the concentration would double?

26 A. That's a fact, that's correct,



1

2 yes.

3 Q. So in fact evaporation would
4 indeed lead to an increase in the level.

5 A. Yes, I was just talking about
6 the possibility of evaporation.

7 THE COMMISSIONER: The digoxin will
8 not evaporate, is that right?

9 THE WITNESS: The digoxin would not
10 evaporate. I think the evaporation will not lead
11 to an increase in the level, because, we should be
12 precise here. Evaporation will lead to an increase
13 in the concentration, okay?

14 Q. Would that not in turn lead
15 to an increase in the level?

16 A. What are we talking, are
17 we talking level or talking concentration?

18 THE COMMISSIONER: We are really
19 talking about the reading, I think, are we not?

20 THE WITNESS: Well, the reading is
21 really imprecise, it is not fitting with the seriousness
22 of this deliberation, I think we should use the
23 word concentration.

24 Q. Well, the reading, Dr.
25 Mirkin, obtained of 491 nanograms per millilitre is
a concentration, is it not?



1 A. You are quite correct.

2 Q. So if we had this sample that
3 was reduced by 50%, or 75% through the process of
4 evaporation, would it not indeed lead to an increase
5 in the concentration?

6 A. Correct.

7 Q. By the corresponding percentage.

8 A. You are quite correct.

9 Q. Because the digoxin would not
10 evaporate.

11 A. That is quite correct.

12 THE COMMISSIONER: The serum would but
the digoxin wouldn't?

13 THE WITNESS: The fluid in the serum
14 would, fair enough. The serum, as you have heard I
15 am sure, is composed of water, salt, protein and some
16 fats.

17 THE COMMISSIONER: I am interested
18 though in what you are saying about the distinction
19 between concentration and level, doesn't the level
signify the concentration?

20 THE WITNESS: Yes. I was thinking
21 about that as we were talking. A reading doesn't mean
22 anything, when you are assaying this material -- I
23 don't want to go through this, you have been through

24

25



1

2 this so often, you obtain a reading on a curve,
3 a number.

4 THE COMMISSIONER: Yes.

5 THE WITNESS: And that number then
6 can be translated into a concentration, that is
7 nanograms per ml. of material, or per gram of tissue.

8 THE COMMISSIONER: I guess we have
9 been using, perhaps wrongly, we have been using the
10 reading and the level as synonymous, that is what
11 we mean.

12 THE WITNESS: Yes.

13 THE COMMISSIONER: We don't even
14 know, I should speak just for myself, perhaps
15 some of the learned counsel do, I have no idea of
what figures you get before you get the final level,
but that is what we are talking about.

16 THE WITNESS: Of course, yes.

17 I think I would correct myself here, we could use
18 level and concentration in synonymous, exchangably,
19 and I think I would consider that perfectly appropriate.

20 Q. Dr. Mirkin, finally the
21 fact that, the mere fact that this sample sat for
22 ten months before the level was read, would that not
23 in your view affect the reliability of the result?

24 A. No, it does not, with the

25



1

2 assumptions that we have discussed previously.

3 Q. That there was no evaporation
4 and that there was no major alteration in the structure
5 through something like boiling?

6 A. Yes. Or another possibility,
7 if someone added a very strong acid or alkali,
8 perhaps that might have modified the digoxin present
9 in this serum.

10 Q. Is that sometimes done in
11 a virology lab?

12 A. Not that I am aware of.
13 I think if you exclude inadvertent mishandling of
14 the specimen, things lie around for a long time, they
15 just do and one can take the specimen and use it.
16 So I would not feel that storage of these materials
17 was in any way -- was to be considered as a reason
18 for questioning the validity of the assay procedure.
19 Do I make myself clear on that?

20 Q. Yes.

21 A. Good.

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Q. Yes. Dr. Mirkin, yesterday

you were asked some questions about medication errors. I would like to pursue that a little bit. I take it that from your experience medication errors do occur in institutions where medications are routinely given.

A. That is correct.

Q. And I believe you said that they are more likely to occur in a pediatric institution in that many calculations are required of dosages.

A. I think that is my perception of a problem that I don't know has received major attention, nor on which there is useful data.

Q. Well, I take it that when you provide opportunity for humans to make errors that indeed they do make errors on occasion.

A. Yes, we are all fallible.

Q. You also mentioned that the method of distribution may affect the number of medication errors that are made; I believe that is what you said. I take it that you are referring to something like the unit dose system.

A. Oh, yes. The method of internal drug distribution in the institution. Is that what you mean when you say distribution?



1

2 Q. Well, I believe those were
3 your words and I just wondered what you meant by that.

4 A. Oh, good. I think that is
5 probably what I was getting at where some greater
6 uniformity can be provided by having the medication
7 made up in a specialized unit and then distributed
8 to the ward where it is to be used in contrast to the
9 manner in which this was carried on at this institution
10 formerly where the material, the drug was prepared
11 at the time it was needed at the bedside of the
patient.

12 Q. And very often by people who
13 were under stress or who had a lot of other things on
14 their mind at the same time.

15 A. Well, I hope they didn't
16 have too many things on their mind. These are pro-
17 fessional individuals, so, I think we shouldn't under-
mine the competency of the staff there.

18 Q. No, of course not. But I
19 take it that the theory of the unit dose system is
20 that it is better to have people who are specially
21 trained in drug preparation to be preparing and
concentrating on the preparation of the doses.

22 A. That is the theory. It is
23 like failsafe, it is as if we can't send a

24

25



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2 missile up unless somebody pushes a button. But the
3 interesting thing is I have often wondered how well
4 the theory has been tested. Now, we introduced -- if
5 I may digress on this for a minute?

6 THE COMMISSIONER: Two minutes.

7 THE WITNESS: We have two minutes.

8 We introduced unit dose into our institution based on
9 a very similar premise. First of all, we were told
10 it would reduce patient costs, which was a nice thing,
even in a capitalist society like ours.

11 Now, the other thing is that we were
12 told it was going to reduce the potential for error.
13 Well, what you do is, you have somebody preparing it,
14 presumably you have somebody checking the preparer
15 and we really have had no data to identify how many
16 errors do come out of a process of that sort. The
17 presumption is, and I think it is a reasonable one,
18 that that is going to have a better check or safety
19 factor than when the drug is prepared under stress in
the hospital at the bedside.

20 Now, is the pharmacist who prepares
21 it under less stress than the nurse when the order
22 comes down for a rush order for something, you know,
it always has intrigued me.

23 Q. But I take it that you are

24
25



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2 not convinced that it is going to be an improvement
3 on the system, but that you don't have any data to
4 establish one way or the other.

5

A. Yes. But I think overall
I would opt out and say yes, this is an improvement
over what we have done and if I were going to modify
the system I would go the way I think it has been
recommended.

9

THE COMMISSIONER: This hospital has
10 done that.

11

THE WITNESS: Has done that. So,
I see nothing -- I am not being critical of it, it is
12 just another perspective balance on this issue.

13

MS. MCINTYRE: Q. I take it that
this whole business about calculation is with respect
15 to the type of error where there is a wrong dosage
given and that the right drug is given to the right
16 patient but the wrong dosage is given.

17

A. That happens, but it could
be the wrong drug being given to the wrong patient.

18

Q. Yes, I was going to get to
that next.

21

A. Yes.

22

Q. I take it you can also have
cases where the right drug is given to the wrong

24

25



1

2 patient. Like in the Inwood situation where Baby
3 Inwood got Baby Pacsai's dosage of digoxin.

4 A. Well, I don't think the right
5 drug is ever given to the wrong patient.

6 Q. Well...

7 A. I know what you mean, but we
8 ought to have that in the record because I don't think
9 that is what you mean, is it?

10 Q. I mean that a drug intended
11 for one patient is given to another patient.

12 A. Yes.

13 Q. And the result of that could
14 be that a patient not prescribed a drug would get it.

15 A. Yes, that must happen.

16 Q. The other possibility is of
17 the same result, that the wrong drug is given to the
18 right patient; in other words, one drug is prescribed
19 and another drug is given in its stead.

20 A. Correct.

21 Q. And both of these are going
22 to lead to a patient receiving a drug that wasn't
23 prescribed.

24 A. That is correct.

25 Q. You told Ms. Cecchetto
yesterday that in your opinion it was unlikely that



1
2 three patients on Ward 4-A/B could have received
3 digoxin and yet not be prescribed it by error. I am
4 wondering how you reached that conclusion, given the
5 fact that there is so much digoxin given out on a
6 ward such as this, that is, a cardiac ward.

7 A. Well, I must say that that is
8 a very subjective interpretation. First of all, it
9 gets back to my feeling about the professional staff.
10 Now, the nursing staff on the intensive care wards are
11 very professional, they don't make one -- slipups of this
12 sort don't occur in a haphazard or random or in a
13 manner that is casual, shall I say. Each patient
14 has a medication record, each nurse, as I understand it -
15 this may not be the practice in this institution, but
16 I presume it would be - each nurse is
17 probably assigned to a given number of patients on
18 the intensive care unit, so, she is assigned during
19 that shift, she watches a certain number of patients.
20 I find it difficult to understand how the incorrect
21 drug could be given to the patient who had not been
22 prescribed the drug. It is much easier to understand
23 how an improper dosage of the correct drug can be
24 given.

25 Q. But you agree with me that
it occurs.



1

2 A. Oh, yes.

3

Q. The Inwood baby is an

4

example. Are you aware that at the same institution
in January of 1982 ---

5

A. No, wait a second. The
Inwood baby is an example of what?

6

Q. Of receiving someone else's
dose of digoxin.

7

A. Okay.

8

Q. Now, in that case the Inwood
baby had had a prescription of digoxin in the past
but when she received the digoxin she was not supposed
to.

9

A. Oh, I thought the baby had
received an improper dose but the drug had been
appropriately prescribed. But that's not what you're
saying?

10

THE COMMISSIONER: No, no, received
somebody else's dose, but she was prescribed
digoxin.

11

MS. MCINTYRE: But the order was
on hold at this time, as I read the chart.

12

A. Okay. Well, that is an
important point.

13

MR. LAMEK: No, I don't think that's

14

15



1
2 right.

3 THE COMMISSIONER: No, I'm sorry, I
4 don't think that's right.

5 THE WITNESS: I'm sorry.

6 THE COMMISSIONER: I think she was
7 put on hold after the error, wasn't that right? Or
am I wrong?

8 MR. LABOW: No, Mr. Commissioner, you
9 are wrong. It was on hold prior to the child receiving
10 the mistaken dose.

11 MS. MCINTYRE: That was my under-
standing.

12 THE COMMISSIONER: Well, then, we had
better check that out because that wasn't my impres-
13 sion, but you are no doubt right if you say so.

14 MS. MCINTYRE: It was on hold, as I
15 understand, there was an order made on March 11th for
16 digoxin 0.0006 milligrams.

17 THE COMMISSIONER: All right.

18 MS. MCINTYRE: And it was on hold,
19 never given and it was on the 12th at 5:30 a.m.

20 THE COMMISSIONER: I have the
21 incident report, but you say the hold was -- all
22 right, I had better make a note of that.

23 MR. LABOW: Mr. Commissioner, the

24
25



1

2 EKG had shown signs of digoxin toxicity on the
3 child's admission and that is why digoxin had been
4 ordered held.

5 THE COMMISSIONER: Okay, I apologize,
6 Ms. McIntyre, you are right. It has happened before.

7 MS. MCINTYRE: The first time, I
believe, Mr. Commissioner.

8 THE COMMISSIONER: No no, no no.

9 MS. MCINTYRE: Q. So, Dr. Mirkin, I
10 think we are in agreement now that this baby had
11 previously been on digoxin but at the time she re-
12 ceived this does in error the order was on hold.

13 A. Okay.

14 Q. So that the patients were
15 confused. I was going to ask if you were aware that
16 at the same institution in January of 1982 there was
17 a confusion not between patients but between drugs
18 where epinephrine was confused for vitamin E on
19 five occasions in one month leading to a patient
receiving a medication that was not prescribed.
20 So, you would agree with me that it does happen.

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A. I think I have agreed with you that it does happen. I also have reached the conclusion that it would be very unusual to have digitalis administered to patients who had not been prescribed that drug or a drug similar to digoxin for their treatment. I still would feel that way. That is not to state categorically that these events could not ever have happened.

Q. That is your subjective impression?

A. It has to be entirely that.

Q. Fair enough.

I would like to ask you briefly about Justin Cook, and I believe that you have been provided with the chart, where the possibility of a medication error has been considered by this Commission and, just to remind you of the sequence of terminal events in this child, on March 21, in the evening, about six o'clock, the child had a severe blue spell and was given propranolol by the doctor and responded immediately and well to that medication. The child experienced another, from what I can gather, similar blue spell, at least the clinical symptoms. at approximately 3:45 and was administered two doses of propranolol, totalling



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D2 2 6 mg. There was no positive response shown. The
3 child went through a series of changes. A sample
4 of blood was taken at 4:30, which gave a level of
5 72 nanograms of digoxin. The resuscitation attempt
6 continued until approximately five o'clock, at
7 which time the child was pronounced dead and, post
8 mortem, there were quite high levels found in the
tissues of digoxin.

9 First of all, I would like to ask
10 you whether, in your opinion, given the fact that
11 the child responded to propranolol at 6:00 p.m.,
12 when he suffered the first blue spell, would you
13 expect him to have responded to the same drug for
the same symptoms?

14 if patients
A. The response/with cyanotic
15 disease to propranolol is very variable. I think it
16 is almost impossible to state with certainty that the
17 patient would have responded to the second dose of
18 the propranolol. We have had extensive experience -
19 and I am sure the cardiologists at Sick Children's
20 are very skilled and knowledgeable about this - where
21 the drug did not produce a satisfactory response the
22 second time around. I would say it is not unusual,
let me put it that way.

23 Q. Would you have anticipated,

24
25



D3 1 in the circumstances, that there would have been a
2 positive response? Is it more likely than not that
3 there would have been a positive response?

A. 5 Obviously, the doctor's
6 presumption was, yes, there was going to be a
7 response, and one does not initiate an intervention
8 in these conditions without the presumption that
9 it is going to be beneficial to the patient. So
10 their presumption was, yes, of course, and it would
11 have been my presumption under the conditions that,
12 yes, I would have got a positive response. But they
13 did not.

Does that infer that something else
14 was given? No. I would not reach that conclusion
15 because of the lack of response.

Q. 15 Atropine was also given and
16 that produced a response shortly after the 6 mg. of
17 propranolol was given.

A. 18 That is correct.

Q. 19 Does that help you in deciding
20 whether or not what was supposed to be propranolol
21 was propranolol, or whether it might have been digoxin?
22 Does that help in any way?

A. 22 No, it really does not. I
23 think there are some suggestions here that this drug

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1
2 might have been propranolol. For example, the
3 heart rate of this patient was 140 beats per minute.
4 At the time the patient had the cyanotic spell,
5 at least according to my records - this is the last
6 one --

7 Q. I had thought, doctor - sorry
8 for interrupting, but I had thought that the 140 heart
9 rate was after the atropine was administered.

10 If you would like to look at the
11 chart, at page 27, or page 29, there is a fairly
12 detailed summary of the events that occurred. It
13 says that the heart rate decreased 80 to 100 beats
14 per minute after the propranolol was given.

15 A. Had decreased; is that
16 correct?

17 Q. Yes, on page 27.

18 A. Yes. Now, the effect of
19 propranolol on heart rate is precisely that. That
20 is, the effect of that drug on the heart rate would
21 be to slow it.

22 Q. Okay.

23 A. Okay. So, I made my state-
24 ment a moment ago in response to your query about
25 whether or not the data in the chart would support
the view that this was or was not propranolol that



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D5 2 was given. Based on that reduction in heart rate,
3 I would tend to conclude that that, indeed, was
4 propranolol that had been given to the patient;
though, of course, there is no precise evidence
5 that, indeed, it was.

6

Q. The response to atropine
7 would be to increase the heart rate?

8

A. That is correct.

9

Q. Why would they want to give
10 two drugs; one to decrease the heart rate and one to
increase the heart rate? I don't understand that.

11

A. That is a good question.

12

I think the reason that the propranolol is given is
not to decrease the heart rate necessarily but to
increase the oxygenation of the blood and, in this
particular patient, to allow blood to circulate
more effectively into the lungs and to become
oxygenated, because this patient had what you
describe as a blue spell - we would describe it
as a cyanotic spell. The blue spell is due to the
fact that the blood is not adequately oxygenated.

19

Q. Can I ask you this, Dr.

21

Mirkin --

22

A. I thought you wanted an

23

explanation.

24

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D6 1
 2 Q. I'm sorry, I thought you
 3 were finished.

4 A. No, I am not.
5 If you do want an explanation, we
6 will do it. If you don't, we don't have to.

7 THE COMMISSIONER: I do.

8 MS. MCINTYRE: I'm sorry.

9 A. That's okay. I am not
10 irritated or anything - it is just that my voice
11 sounds that way.

12 That is an excellent point: Why
13 do you give a drug that might slow the heart rate
14 and then follow that up the next moment with one
15 that will increase it?

16 You asked that question and I was
17 trying to respond intelligently to it.

18 The drug is given, the propranolol
19 is given to increase the oxygenation of the blood;
20 not to slow the heart rate, but drugs have all kinds
21 of strange effects. This drug will relax certain
22 blood vessels, allowing more blood to get into the
23 lungs, get oxygenated until the baby gets pink. That
24 is the real objective of the propranolol.

25 Q. That did not occur in the
26 second case?



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D7 2

A. It did not the second time,

3 that is right.

4 Q. The heart rate slowed but
5 the baby did not get pink.

6 A. Exactly correct.

7 Now, the physician, when confronted
8 with that situation, said, well, we had better give
9 something because if this baby's heart rate gets too
10 low, this baby will go into acute congestive failure
11 and die on us. So, they gave atropine, which tended
12 to increase the heart rate, and that is the 140 I
13 think we are talking about - from 80 to 140. So,
14 that is the basis for that manoeuvre.

15 I hope that is reasonably clear.

16 Q. I think I understand that.

17 Can you tell me whether, if digoxin
18 was in fact given, rather than propranolol, at 3:50
19 or 3:55, is it possible that the effects of that could
20 have resulted in the death of the child within
21 approximately half an hour to forty minutes?

22 THE COMMISSIONER: I think we had
23 that exact question yesterday, but we will try it
again and see if we get the --

24 MS. MCINTYRE: I am not sure that I
25 understood the answer.



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THE COMMISSIONER: Do we not have

that question, I think almost in those words?

THE WITNESS: I hope I am giving the same answer.

THE COMMISSIONER: Yes.

THE WITNESS: It is terrifying.

My sense of it is, yes, certainly, the effects might be manifest, provided that the patient received a sufficiently large dose.

As I understand my calculations here, this patient did not receive a very large dose because, even if the digoxin was given - and let us assume the pediatric dose --

MS. McINTYRE: Q. Let us assume an adult dose because I think we all know that if it was a pediatric vial of digoxin, it would be a very, very small dose.

A. Yes. I think you have heard testimony from Dr. Kauffman and probably from Dr. Spielberg as well.

This would have come out roughly I think, according to my calculations, at about 150 micrograms total dose; correct? If one used the adult vial, making that assumption.

Q. Okay.



D9

A. That is a good dose of drug
and it might have produced some adverse effects.
I think, though, if you go further and ask me whether
that would produce the blood level of 100 micrograms
per ml. that we saw - or was it?

Q. 72.

A. 72, I beg your pardon. I
don't think that we could really buy that.

Q. And you are basing that on
the same calculations as Dr. Spielberg and Dr.
Kauffman used?

A. I think reasonably on that
premise and even on my own calculations that we did
at Minnesota.

THE COMMISSIONER: You will be happy
to know, doctor, that that is what you said yesterday.

THE WITNESS: Senility has not set
in too quickly.

MS. MCINTYRE: Thank you very much.

THE COMMISSIONER: Thank you, Ms.
McIntyre.

Mr. Young, I think you said you were
not going to question this witness; is that right?

MR. YOUNG: I have no questions, Mr.
Commissioner.



D10

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2 THE COMMISSIONER: Mr. Knazan.

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CROSS-EXAMINATION BY MR. KNAZAN:

Q. Doctor, my name is Brent Knazan and I represent Marianna Christie. She is a Registered Nursing Assistant.

I would like to ask you about Baby Jesse Belanger, who is your No. 18.

This baby you put into your second category because there was digoxin in tissue after exhumation even though no digoxin had been prescribed.

A. Please go on.

Q. You put it in your second category for that reason and I understand that the most you can say is something qualitative; that is, there was digoxin in the baby and the digoxin had not been prescribed.

Can we not say a little more than that?

Maybe I should first refer you to Mr. Cimbura's findings, on which, I presume, you relied. That is 95E of the Cimbura document, September 29, 1982.



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2 A. I don't have that, those
3 numbers.

4 Q. It is just two readings and I
5 can put them to you.

6 THE COMMISSIONER: I will give you
7 that, Doctor, there it is and I will get my own out.

8 MR. KNAZAN: Thank you.

9 THE WITNESS: Thank you very much.

10 Okay.

11 MR. KNAZAN: Q. 253 nanograms in
12 liver and 43 in muscle, those were the only two readings
13 and the baby was not prescribed digoxin. So we can
14 say at least not only was digoxin given, that is once
15 we are starting from the premise that this is the
cause of death, but that enough was given to cause
16 the baby's death, that is part of the premise?

17 A. That is your premise?

18 Q. No, you put it in your second
category.

19 A. Yes.

20 Q. And I understood from your
evidence that the reason you put it in your second
21 category is that there was digoxin in tissue?

22 A. Yes, okay.

23 Q. And no digoxin was prescribed?

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A. Okay, yes.

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Q. So starting from it being in your second category, we can at least then say something more, and that is enough was given to cause death, if that was the cause of death?

A. Yes, I think that one would have to conclude that.

Q. With this limited data, the baby was five weeks old with a birth weight of 3,080 grams, I don't have the weight just before death that I have been able to find, are you able to say anything about the minimum amount of time that would have been required for the digoxin which caused the death to distribute into the baby's body; that is are you able to give a time, at least a minimum amount of time prior to arrest that the administration would have occurred?

A. Yes. Then the assumption, the further assumption I guess must be made that the route of administration in this child was into the thigh, or not? I think as you recognize that is going to significantly influence the time parameters that are selected.

Q. All the assumptions that Dr. Spielberg, MacLeod and Kauffman made, and that



E.3

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2 was they have specifically referred to location, but
3 only that it was administration by I.V. So perhaps
4 you could answer on the assumption that it was the
5 place of entry, was the place where it would take the
6 least time to kill the baby?

7

THE COMMISSIONER: The I.V., what is
it normally?

8

9 THE WITNESS: The intravenous, well,
10 it can be the arm, it can be the jugular vein through
here (indicating), in some babies it can be a scalp
11 vein. I don't know what the I.V. route was on this
12 child.

13

14 Let us assume, and I think it is a
15 reasonably safe assumption that regardless of the
16 site at which the I.V. was presented, it very rapidly
17 would get into the circulation and it is almost an
18 instantaneous injection. Now, one has to make
19 certain kinds of assumptions here. I am sure you have
20 heard these but I think I have to go through them
21 quickly. One is if the material is injected directly
22 into the vein at a site very close, proximal is the
23 term, very close to the vein, that means one could
24 pump the drug in very rapidly within the course of
25 less than a minute. Under those circumstances one
would be injecting a bolus of drug, a high concentration



E.4

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2 in small volume, and that of course would allow
3 almost instantaneously, well, let us say within
4 minutes, high concentrations of the drug to be
5 achieved in a variety of different tissues.
6
7 Depending, and I didn't see this mentioned in some
8 testimony, depending on the blood flow to different
9 organs. Now these drugs are carried by the blood and
10 if an organ for one reason or another has impaired
11 blood flow the drug will not be distributed to it
12 very effectively. Now in this case the patient's
13 liver had substantial concentrations and also in the
14 muscles. I would say that one could see toxic effects
15 from an overdose given I.V., oh, within half an hour,
16 probably half an hour to an hour, reasonably, and one
17 might even see them earlier.

18 Q. Would less than half an hour
19 be unlikely?

20 A. Depending again on how much
21 was given. If it was given in the manner I just
22 described one could see toxic effects within 15 minutes.

23 Q. You indicated to Mr. Lamek that
24 you had read Dr. Spielberg's evidence to this
25 Commission?

26 A. Not word for word, but I read
27 as much of it as I could, yes.



E.5

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Q. And you read Dr. Kauffman's report, or his evidence?

4

A. I have looked through it, yes.

5

Q. But not the eight volumes or so of evidence?

6

A. No, I just have his summary.

7

Q. I just want to put one question and answer from Dr. Kauffman's testimony and just ascertain, I think you are slightly disagreeing with him and perhaps you can clarify it for me. The question was, this is page 8059 of Volume 83.

12

A. Is that available?

13

THE COMMISSIONER: Yes, it probably is, 8059 of -- ?

14

MR. KNAZAN: Q. 8059 of Volume 83.

15

16

A. If you want to read it I will try and follow you.

17

Q. Yes, I am reading at line 24:

18

"It is my understanding that digoxin was found in the tissues after exhumation. Doctor, am I right in saying that because digoxin was found in the tissues, ... "

22

23

MR. YOUNG: Excuse me, Mr. Knazan, I wonder if you might give the doctor the page number.

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E.6

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2 MR. KNAZAN: Q. I am sorry, 8059 of
3 Volume 83. I am starting at the last line of the
4 page, line 24, the first part is just an introduction
5 to the question:

6

7 "It is my understanding that
8 digoxin was found in the tissues
9 after exhumation. Doctor, am I right
10 in saying that because digoxin was
11 found in the tissues, it would be
12 unlikely that the dose could have
13 been given to that child within an
14 hour of death because that would not
15 have allowed for - had it been given
16 within an hour it would not have had
17 time to distribute?

18

19 "A. Well, there probably is some
20 distribution within an hour, but it
21 is hard to predict in a given patient
22 to what degree, and the concentrations
23 of course achieved would depend on
24 the dose. It is hard, as I said, to
25 quantitate the concentrations in the
liver. I think we have to say that
some distribution did take place in
this child. To what degree we do not



E. 7

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2 "have enough information to speculate
3 about that.

4 "But I think that it is unlikely
5 that the dose was given much less
6 than an hour because there is some
7 digoxin in the skeletal muscle and
8 in the liver. There are so many
9 uncertainties in this patient because
10 of lack of information that it is
11 very difficult to be specific about
12 that."

13 Do you more or less agree with that?

14 A. No, I don't.

15 Q. You don't agree with that?

16 A. I think it is possibly more
17 specific.

18 Q. More specific?

19 A. There are some studies, and I
20 think studies that we have done in our laboratory,
21 which show the distribution of this drug to the
22 skeletal muscle in animals, pregnant animals, and
23 the time frame is much shorter. Now whether that has
24 application to the clinical, to the human situation,
25 must be considered, but I would say that in the
animal model one can certainly see distribution to



E.8

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2 these tissues. To say that distribution is not
3 occurring early on is not what Dr. Kauffman is saying.
4 Dr. Kauffman is saying that distribution, in his own
5 words, does go on and indeed he is perfectly correct
6 in that. The rate at which the compound gets into
7 different tissues varies, as you know. There is a
8 rate constant for movement of these drugs, these
9 molecules, into different tissues. The rate at which
10 that occurs will ultimately determine the concentration
which is achieved as steady state.

11 The point I am trying to make is that
12 if the drug is given in I.V. manner in a bolus
13 injection, I would say that one could find a rather
14 ubiquitous distribution. However, it is clear that
15 the earlier - the shorter the duration after injection
16 the lower the concentration probably. The higher
17 concentration would be achieved after a longer period
of equilibration or distribution as you have said.

18 Well, I don't know whether we really
19 differ on this, Kauffman and myself, or Spielberg,
but I think I would conclude that even in a relatively
20 short time the time frame of half an hour that I gave
21 you, that one might, one would find as I say, I will
22 be more specific than that, drug in the tissues.

23

You see, if one postulates that one

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E.9

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2 is going to produce an effect with a drug within
3 half an hour well it must reach the tissues, correct,
4 you follow that, don't you?

5 Q. Yes.

6 A. Good.

7 Q. It would have had to cause
8 death as well?

9 A. Well, whether it necessarily
10 would cause death I don't know, but it would produce
11 an effect. Now if the concentration is high enough
12 obviously it will produce an adverse effect that might
13 lead to death.

14 Q. You answered that very
15 thoroughly. Could we just turn to Justin Cook.

16 A. Excuse me, I have one of the --
17 MR. YOUNG: That is all right, you
18 can keep it for a while.

19 THE WITNESS: Thanks.

20 MR. KNAZAN: Q. When you testified
21 the first day, on Tuesday, about Justin Cook, you
22 were concerned with the accuracy of the time of the
23 sample taken during the course of arrest; I am
24 referring to Dr. Mirkin's evidence at page 8869 of
25 Volume 87 on Tuesday. Certainly that is where
26 Mr. Lamek's question is. You were very concerned



E.10

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2 about the time of the sample being precise, page 8872;
3 you raised Cook from 0 to 9, and you said:

4 "I think, if the data, in reviewing
5 this again, if those time points
6 are actually precise, and I conclude
7 they might be, or it is not certain,
8 but, if they are precise, then I think
9 we can switch this to a rating of 9
10 based on that technical distinction."

11 Am I right in interpreting your:

12 " ... or it is not certain but,
13 ... ",

14 as recognizing that even though death was pronounced
15 at a certain time it might have occurred earlier
16 during the resuscitation attempt, is that what you
17 meant by that or something else?

18 A. No, that is not what I actually
19 meant and I am sorry it came out in this ambiguous
20 manner. What I was attempting to get at was really
21 the time frame between death and that final blood
22 specimen, the one at 0430, I had assumed that that
23 was a post mortem specimen. As we have heard through-
24 out these last few days, the scoring system was based
25 on the use of ante mortem information not the post
 mortem.



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Now, I made the switch here in the testimony when I was informed that this was indeed an ante mortem level. I had interpreted it as a post mortem level and that was strictly my own interpretation based on the information I thought existed in the chart. Now we know that it is ante mortem and I think that when an individual presents with that concentration of drug in the body one has to think very strongly of intoxication as a consequence of it.

Q We have heard evidence, I can refer anyone to it, that the pronounced time of death is not necessarily actual death in the sense that death can occur during resuscitation and the choice of the pronounced time of death might be arbitrary, would that make a difference?

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Would that make a difference if the sample was indeed post mortem in that sense?

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A. Well, I would say this much, that in this particular individual if that was indeed a post mortem specimen it might have some bearing on the quantitative magnitude of the serum level and concentration that we assayed in that specimen, but the fact remains that that drug was there.

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Q. And the baby was not prescribed it.

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A. And was not supposed to be there and I think that is a very disturbing fact.

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Q. Just one other point. Yesterday in answer to Ms. McIntyre's question I believe you testified that a person with a modest degree of experience could see a dig. effect on the oscilloscope if a baby was on a cardiac monitor and then she asked you by that do you mean doctors and you said yes. I want to make that very clear by modest degree of experience you weren't referring to a nurse on the cardiac ward.

A. Oh. Well, I think what we ought to do is restrict that to cardiologists. Well, you know, I think many of the nurses are very skilled



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2 in being able to discern these findings as well and
3 it would not surprise me to find that many of the
4 nurses on the intensive care ward could also pick up
5 those findings very easily.

6 THE COMMISSIONER: It is the cardiology
7 ward that we are perhaps concerned with. Is that what
8 you meant by the intensive care?

9 THE WITNESS: Oh, I'm sorry, I guess
10 I am using that incorrectly as a matter of fact.

11 THE COMMISSIONER: The cardiology ward
12 is a special ward but not an intensive care ward, or
13 at least they have an intensive care ward as well.

14 THE WITNESS: Okay. I have been using
15 these interchangably and I think incorrectly.
16 We have a situation where many of the cardiology
17 patients are cared for in the intensive care unit, I
18 am sure that is true here as well, is it not?

19 THE COMMISSIONER: It is true as well
20 but our concern is mainly with the cardiology ward, not
21 the intensive care ward.

22 THE WITNESS: Okay.

23 THE COMMISSIONER: There was only one
24 baby, Pacsai, that died in the intensive care ward.

25 THE WITNESS: Well, I hope that hasn't
26 been confusing to anyone. Certainly the nursing staff



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2 it?

3 MR. KNAZAN: Well, I noticed you
4 writing yesterday, Mr. Commissioner.

5 THE COMMISSIONER: Well, I am writing
6 but I am not too sure I know what I am writing, that's
7 the point. I had just thought it was a monitor and
8 I thought that anybody could read it but now you are
9 leading a question as to whether this monitor can be
read. Is that it?

10 MR. KNAZAN: Whether it is as good an
11 indicator as a printed EKG sheet if someone activates
12 the printout. That is all I am trying to establish.

13 THE COMMISSIONER: We have had all
14 kinds of evidence of nurses having noticed the monitor
15 showing some sudden heart change in the baby. Are you
questioning whether they can do that on a monitor?

16 MR. KNAZAN: I am questioning whether
17 a person with a modest degree of experience could
18 see a dig. effect.

19 THE COMMISSIONER: Yes, all right.

20 THE WITNESS: I can answer your
21 question, the one you just raised, and that is, that
22 the twelve channel information is obviously much more
23 informative than the lead to, so to speak, on the
oscilloscope, that you can see on the oscilloscope,

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I think that is generally accepted. However, I would stick to the view that with major arrhythmias occurring I would be willing to bet that 90% of the nursing staff on that unit could pick it up and I would bet if it is done they are skilled there.

6

MR. KNAZAN: Thank you. Those are all my questions.

8

THE COMMISSIONER: Yes, all right.

9

Thank you. Mr. Olah?

10

MR. OLAH: Sir, did you wish to take your morning break before I commence my examination?

11

THE COMMISSIONER: The answer is no because we started at 9:30 but if you're not ready perhaps Mr. Labow will spare you.

14

15

MR. OLAH: No, I am ready to proceed, sir.

16

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THE COMMISSIONER: Or did you want to take a morning break?

18

THE WITNESS: I have a problem.

19

THE COMMISSIONER: Oh, by all means.

20

21

THE WITNESS: No, no, it is not a real desperate one. I was asked to read something last night and I didn't read it very well.

22

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THE COMMISSIONER: Was that by Mr.

24

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Olah?



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2 MR. OLAH: That is correct, sir.

3 THE COMMISSIONER: Well, I don't know
4 that you are under orders to do that.

5 THE WITNESS: Oh, no, no.

6 THE COMMISSIONER: I don't think you
7 need apologize too much for it.

8 THE WITNESS: I am apologizing, I
9 want to be a very cooperative witness.

10 THE COMMISSIONER: Well, how long is
11 this article, whatever it is? We may have to take
12 two breaks but we obviously couldn't take a break --
13 well, I suppose we could take a break now, but we
14 will go on until 1:00.

15 MR. OLAH: Well, maybe I can assist
16 you, sir. What I was hoping to do was, I had
17 asked the witness to read my cross-examination of
18 Dr. Hastreiter in an effort to speed up my cross-
19 examination, basically talking about time and ---

20 THE COMMISSIONER: Well, can you
21 save that to the end? I don't know how long you are
22 going to be. How long are you going to be?

23 MR. OLAH: Well, that was going to
24 be the bulk of my examination. I can get started
25 on something else, but that's the bulk of the
examination.



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THE COMMISSIONER: Well, how long was
your cross-examination? If it was a half an hour it
will take him a half an hour to read it.

5

MR. OLAH: Well...

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THE COMMISSIONER: Let's see if we
can spare this. Mr. Labow, can you go on now?

7

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MR. LABOW: Mr. Shinehoft is prepared
to go on.

9

10

THE COMMISSIONER: Mr. Shinehoft, can
you go on?

11

MR. SHINEHOFT: Yes, sir.

12

13

14

THE COMMISSIONER: All right. Well,
you stand down and we will take Mr. Shinehoft now
and then we will take you after the break. Is that
appropriate?

15

16

MR. OLAH: Perfect, thank you
very much, sir.

17

18

19

20

THE COMMISSIONER: We have a great
habit for ruining breaks for witnesses. You see, the
rest of us just go out and drink coffee, but you have
to read.

---Discussion off the record.

21

THE COMMISSIONER: Yes, Mr.

22

Shinehoft?

23

MR. SHINEHOFT: Thank you, Mr.

24

25



1

2 Commissioner. I don't know how much help I am going
3 to be because I don't intend to be very long.

4 THE COMMISSIONER: Well, I am not the
5 one to encourage you to be any longer.

6 MR. SHINEHOFT: But if you really want
7 me to, I will.

8 THE COMMISSIONER: No.

9 CROSS-EXAMINATION BY MR. SHINEHOFT:

10 Q. Doctor, my name is Jack
11 Shinehoft and I represent the parents of the baby,
12 Kevin Pacsai, and I believe you have given evidence
13 that you personally were the doctor to review this
child, is that correct?

14 A. That is correct.

15 Q. I believe you are aware,
16 Doctor, that this baby attended at three different
17 hospitals on three different occasions. Did you
18 examine all three hospital records?

19 A. Yes, in my notes I have observa-
20 tions that were made at St. Joe's Hospital, at
21 McMaster and at Sick Children's, is that correct?

22 Q. That is correct, Doctor. You
23 are aware that this baby attended St. Joseph's
Hospital first and then went to McMaster and then was

24

25



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2 finally transferred to the Sick Children's Hospital.

3 A. That's my understanding.

4 Q. Did you know why he was
5 transferred to Sick Children's Hospital; in other
6 words, was it for treatment purposes or was it for
7 what they call a workup purpose?

8 A. If I may go back to St.
9 Joe's for a minute. This patient presented with a
10 description of heart speeding up and slowing down.
11 So, there was some evidence of an arrhythmia at this
12 time. This is on March 7th of 1981.

13 Q. Yes.

14 A. The patient actually became
15 very ill at St. Joe's Hospital and experienced
16 shock and was treated very aggressively. Is that
17 correct so far?

18 Q. That's my understanding,
19 Doctor.

20 A. Yes. And then on March 8th
21 I believe the baby was transferred to McMaster, or
22 was it on the 7th, I have here on the 8th, and the
23 baby seemed to be doing reasonably well at McMaster,
24 good color, profusion was good, but the baby did
25 need some supportive therapy at the time and was
placed on digitalis at McMaster. Actually, the baby



Mirkin
cr. ex. (Shinehoft)

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2 was given some digitalis at St. Joe's Hospital as
3 well, I have a small dose here. Is that correct
4 so far?

5 Q. That is my understanding as
6 well, Doctor.

7 A. Yes. And then the baby was
8 transferred to Sick Children's Hospital, I would pre-
9 sume, because there was still some difficulty in get-
10 ting the heart rate to slow down. It was my under-
11 standing that the child was brought here for treat-
12 ment and I would presume maybe further diagnosis.

13 Q. Would you care to comment
14 on the child's condition upon his arrival at the
15 Hospital for Sick Children?

16 A. Well, I have a note here.
17 On March 11th -- now, the baby was in McMaster on
18 March 8th, 1981 and I presume the transfer, was it
19 completed on March 11th, to Sick Children's Hospital?

20 Q. That is correct, Doctor.

21 A. At 3:30 my notes indicate
22 the baby had a heart rate of 150 with a normal
23 rhythm, everything else looked pretty good, chemistries
24 looked good. I have here, "considered stable." I
25 have taken that out of the record.

Q. Yes, other doctors have

24

25



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2 given evidence, Doctor, that they felt that upon his
3 arrival at the Hospital for Sick Children the baby
4 was relatively stable and in relatively good condi-
5 tion. Would you agree with that?

6 A. I think from the record one
7 has to conclude that. Now, that is at 3:30?

8 Q. Yes, upon his initial ar-
9 rival at the hospital.

10 A. Yes.

11 Q. And you indicated in your
12 evidence, Doctor, and I can refer you to the page and
13 line number, that you did not consider the death of
14 this baby unanticipated. It would be a logical conse-
15 quence of what we observed. I believe you meant, and
16 correct me if I'm wrong, Doctor, that this was as a
result of his being given an overdose of digoxin, is
that correct?

17 A. That is my intent, yes.

18 Q. Now, would you expect this
19 child to die or to have died based on the clinical
20 picture if there had not been this digoxin administered?

21 A. I don't believe I would
have anticipated that.

22 Q. Well, you also indicated in
23 your evidence, and I have the page and reference

24

25



1

2 number, Doctor, it is page No. 8904, line 13, that
3 you have no explanation for the elevated potassium
4 levels in this child. Do you recall giving that
5 evidence, Doctor?

6

THE COMMISSIONER: What page?

7

MR. SHINEHOFT: 8904.

8

THE COMMISSIONER: What volume is
that?

9

MR. LAMEK: Volume 87.

10

THE WITNESS: Yes, I recall it.

11

12

MR. SHINEHOFT: Q. You recall giving
that evidence?

13

A. The basis for that state-
ment ---

14

15

Q. Well, I wanted to talk to you
about the basis of that statement.

16

17

18

19

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A. Yes, the basis of that state-
ment, when I reviewed the medication record there was
an increase in potassium from 3.7 to 7.7 in less
than 12 hours and I could find no administration of
potassium noted. I couldn't find it, but perhaps
it was there.

21

22

23

Q. But is it not true, Doctor,
that an elevated digoxin level will cause an elevated
potassium level?

24

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Mirkin
cr. ex. (Shinehoft)

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A. I have heard that bandied
about.

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Q. Well, Dr. Kauffman says
that there is literature that would indicate that
this is in fact the case and he has given evidence
about the concept of the competition for the binding
sites and the moving of the potassium which is, and
correct me if I am wrong, an intracellular solution
or substance outside the cell. Is that not correct,
Doctor?

A. Well, that can occur and I
think we have published data in the New England
Journal on such an effect occurring in patients
receiving digitalis intoxication and that is available
for you. But the change in serum will require a
tremendous amount of potassium coming out of the cell.

Q. Well, isn't it true that
approximately, I have the exact ---

THE COMMISSIONER: I'm sorry, change
in the ---

THE WITNESS: Serum concentration
of potassium from 3.7 to 7.7, in my opinion, would
require an awful lot coming out of the cell based on
the mechanism that you are proposing. Do you follow
me?



1

2

MR. SHINEHOFT: Q. I understand that.

3

But it is my understanding, Doctor, that if you had a
level of 100 potassium inside the cell that you would
only have something like 4.5 nanomoles per milli-
litre outside the cell. Would you agree with that?
That is, for the most part, the great majority of
potassium is inside the cell as opposed to outside
the cell.

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A. That's all correct, that's
all correct.

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DPrc

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Q. Dr. Kauffman has given evidence
that there could be a shifting from inside to
outside the cell in a number of ways, one of which
is through the administration of digoxin and the
competition for the binding sites and another way,
of course, is if the pump breaks down completely,
if there is an overwhelming amount of digoxin then
the pump might be shut off.

Again, would you agree with those
possibilities, doctor?

A. I would agree with the
analysis of the mechanism of action or the analysis
that digitalis affects both those processes, yes,
with what you have said. I would
agree with the fact that the digitalis can influence
the intracellular accumulation of potassium.

What I think I have some trouble
with is presuming that the amount of potassium
released by the administration of digitalis could
be responsible for producing an increase of an
almost 4 to 5 milliequivalents per litre of potassium.
One way that might have occurred is if you have
cell death - that is one thing - and the potassium
just gets extruded out into the circulation.

Q. Death of the tissue, and that

24

25



1

G2 2 is why he had such an elevated reading after death.

3

4 Some of the pathologists have
5 said that they are not concerned about potassium
6 levels in serum after death because it is released
7 by the cells.

8

9 Do you agree with that, doctor?

10

A. I think I would certainly be
11 in agreement with that particular position, yes.
12 However, we are talking now about ante mortem change
13 of about 4 or 5 milliequivalents - that is a lot; I
14 don't care what anyone says.

15

Q. I am aware of that.

16

A. I am sure you are. That is a
17 lot. I am not that willing to accept at this hearing
18 that that could have been induced by the mere
19 administration of digoxin.

20

What I would like to do, if I may,
21 is to perhaps make some attempt at making a calcula-
22 tion for you on that and submitting it to you.

23

Q. I have had the calculations
done, I can tell you, doctor.

24

Let me ask you a couple of other
things before we get into the calculations.

25

First of all, do you agree that his
renal function was not abnormal? He had a normal BUN.



G3 2 Is that correct?

3 A. As best we can tell, that
4 is normal, yes.

5 Q. Less than 5, I think it was.

6 A. I think that is certainly --
7 I would agree with you on that.

8 Q. And that he was not
9 administered any potassium, according to the drug
information that we have.

10 A. That is my understanding as
11 well.

12 Q. It is my understanding that
13 if you did the calculation and he had no renal
14 function whatsoever, making that assumption, then
15 the body could not endogenously - that is, of itself -
16 produce the level of increase that occurred in this
child; would you agree with that?

17 A. That the body could not...?

18 Q. In other words, if the kidneys
19 were shut off completely and you just had it compounding
20 the effect of potassium, it would not have risen
21 from the level of 3.7 to 7.7 in the timeframe that
occurred in this child.

22 A. In less than 12 hours?

23 Q. That is right.

24

25



G4

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A. That is probably a reasonable assumption.

2

Q. So, therefore, would you not agree that something else, other than lack of renal function, must have happened? Is that a fair assumption?

3

A. I think that is what I am getting at.

4

Q. What do you say happened?

5

A. I don't know. I don't know whether this patient was inadvertently administered potassium - that is one scenario.

6

Q. We don't have any drug medication error reports, which is commonplace and normal, is it not, in a hospital where there has been a drug inadvertently or by error administered to a patient?

7

A. There is no record when a drug is administered by error; you don't have --

8

Q. If it is a known error.

9

A. Exactly. We did not have any information that digitalis was given to these kids either, but we determined digoxin was present by analyzing for it. The same reasoning could apply here. We have analyzed and have found potassium in

10

11



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G5 2 the serum of this patient. How did it get there?
3 You would suggest it is there because of the effect
4 of another drug. I might take the argument and say,
5 well, that potassium was given as potassium to this
patient.

6

Q. If you accept that, doctor,
7 let me ask you this: It is fairly commonplace, is
8 it not, for small babies with congenital heart
9 problems to be administered digoxin?

10

A. Correct.

11

Q. Would you say the same is
true of potassium?

12

A. Absolutely not.

13

THE COMMISSIONER: What is the
14 effect of administering potassium?

15

THE WITNESS: Generally, to decrease
16 the heart rate and decrease the excitability of
17 the heart. Those are effects that are quite opposed
18 to digoxin effects.

19

MR. SHINEHOFT: Q. So, you would
agree with me, doctor, that it is common to administer
digoxin in the environment in which this baby was
placed but not very common to have potassium
administered?

23

A. Very uncommon, unless the

24

25



G6 1
2 doctor felt that there was some reason to give
3 potassium to the patient.

4 Q. His potassium, on arrival
5 at the HSC, I can tell you was 3.9. My understanding
6 is that that is fairly normal. Is that correct?

7 THE COMMISSIONER: I have forgotten
8 now. Was this not the one that Dr. Kauffman
9 administered something to --

10 MR. SHINEHOFT: He administered
11 something, Mr. Commissioner, to reduce the amount of
12 potassium.

13 THE COMMISSIONER: What was it,
14 though? Did he not administer something? What
15 drug did he administer?

16 MR. SHINEHOFT: He gave him an
17 enema and he gave him a glucose solution, and there
18 was one other thing that he did that I can't recall.

19 THE WITNESS: Did he give him
20 insulin?

21 MR. SHINEHOFT: Q. He may have
22 given him insulin. There were three things that he
23 did. He gave the baby an enema, gave him glucose
24 and may very well have given him insulin as well.

25 THE COMMISSIONER: This is purely
26 academic but if potassium has the opposite effect of



G7 2 digoxin, if there is digoxin toxicity, I take it
3 no one ever administers potassium to correct that?

THE WITNESS: No, definitely. That was used for the treatment of digitalis intoxication and, in adults, it still can be used. We sometimes might try to correct this imbalance in infants as well.

THE COMMISSIONER: I take it this
does not happen very often that they do that? The
general cure for digoxin intoxication is to hold the
digoxin, I take it. What about the child taking
a dose by accident? Do they ever give potassium for
that?

THE WITNESS: Potassium has been given, certainly, in the treatment of acute intoxication, propranolol is used; a variety of compounds.

But, to get back to your question --

17 MR. SHINEHOFT: Q. Just to follow
18 up on that, just one question arising out of that.

19 My understanding, doctor, is that
20 where there is a high digoxin level in the body, the
21 body produces potassium to try and combat that
digoxin; is that not correct, doctor?

22 A. It comes as news to me. I'm
23 sorry, I don't mean to be facetious.



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G8 2

Q. Well, some people think
that. Are you not aware of any literature that
would be supportive of that proposition?

A. Let me put it this way: The
proposition you are putting before me is supported
by effects of digitalis/digoxin on the pump
system on a shift in intercellular potassium, I
do not think there is any question about that. That
is to say that it does do what you have described.
What you have described to me is not inaccurate; it
is correct.

The point I am raising is: Does
the digitalis effect on intercellular potassium
allow us to interpret this increase observed in this
patient as being attributable to that effect?

I would take the position that that
is one explanation. My own view is, I don't think
it is sufficient in this patient, particularly this
patient with normal renal function, where extra
potassium presented to the kidney would be cleared.
This is essentially a pretty healthy kid in some ways.

Q. I understand that.

A. So, I would have anticipated
if the digoxin was allowing extra potassium to come
out of the cells and into the circulation, a lot of it



1

G9 2 would have been cleared. One could go further and
3 say, well, a very, very large amount had come out of
4 the cells as a consequence of the digoxin action and
5 could not be cleared. I would say, well, the amounts
6 coming out, I don't believe were that large to
explain it.

7

Q. So, you say that is a
possibility, although there are other possibilities?

9

A. I would leave that open.

10

Q. One of the other possibilities
you suggest might be that he received potassium,
although you would agree with me that the probability
of receiving potassium in error is less likely than
digoxin because of its lesser frequency of being
administered?

15

A. I would agree with that, yes.

16

Q. Do you have any other
possible explanations as to the elevated potassium
level in this child?

19

A. Unless the sample -
perhaps you could give me this information - was
hemolyzed -- I assume it was a normal sample.

21

Q. No, it was not. There was
a hemolyzed sample that was 11.9, I believe, or 11.7,
and then there was, almost immediately after that,

24

25



G10

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another sample that was drawn, and that was a non-hemolyzed sample.

4

I could refer you to the chart, doctor. It is Exhibit 106.

5

6 Perhaps, Mr. Registrar, you could...

7

THE COMMISSIONER: I have it at

9, at page 83.

8

MR. SHINEHOFT: 9.0.

9

10 THE COMMISSIONER: And the non-hemolyzed one was 7.7.

11

MR. SHINEHOFT: That is correct.

12

13 Q. If you turn to page 83, doctor, of the medical chart - have you got that page?

14

A. Yes, I am with you.

15

Q. You will see, about halfway down the page, the potassium readings.

16

Have you found that?

17

A. Yes.

18

Q. If you go across, you will see 3.9 is the first reading.

19

A. Right.

20

Q. And then it is 9.0.

21

A. Yes.

22

Q. And it says above that, "see C". Do you see that, doctor?

23

24

25



G11 1
2 A. Yes, I am with you. "Slightly
3 hemolyzed."

4 Q. It says "slightly hemolyzed"
5 and, then, to the right of that, there is a third
6 sample, 7.7, and do you see above it, it says "see D"?

7 A. Yes.

8 Q. What does that say, doctor?

9 A. "Not hemolyzed".

10 Q. So, would it be fair to
exclude that possibility then?

11 A. I have accepted what you said.

12 Q. Are there any other possi-
13 bilities for the high potassium levels that this
14 baby exhibited?

15 A. None that really seem logical
for the time being.

16 This patient was on a diuretic that
17 might have led to some potassium accumulation but I
18 don't think that is really an important consideration,
19 frankly.

20 Q. Just to summarize it, you are
21 saying it could be the digoxin or it could have been
22 potassium that was administered in error to this child?

23 A. I think I would have to just
conclude that, yes. Those are the two major

24
25



G12

1 possibilities.

2
3 MR. SHINEHOFT: Thank you very much,
4 doctor. Those are all the questions I have.

5 THE COMMISSIONER: I think we will
6 take 20 minutes now, but if you need longer, Dr.
7 Mirkin, will you let us know.

8 THE WITNESS: Thank you.

9
10 --- recess.

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---Upon resuming.

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THE COMMISSIONER: Yes, Mr. Olah.

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MR. OLAH: Thank you, Mr. Commissioner.

CROSS-EXAMINATION BY MR. OLAH:

Q. Doctor, I am much obliged to you for reading the passages I referred you to, they were passages for your reference, Mr. Commissioner, of my cross-examination of Dr. Hastreiter.

9 Doctor, are you in agreement with the
10 evidence that was offered previously that the first ef-
11 fects of digoxin after an intravenous
12 administration of a lethal dose, let's talk about
13 something in the order of an adult vial, will be seen
somewhere after, in the range of 5 to 30 minutes?

1

15

A. I think that is correct, I would accept that.

16

Q. And that if there was an oral administration of that magnitude that the first symptoms or evidence of digoxin toxicity would be seen somewhere in the range of the two hours?

20

A. Yes, I think two hours is reasonable. One might reduce it perhaps to an hour, or an hour and a half, let's say two hours is acceptable. You want to be how tight?

23

24



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2 the outside parameter, that is, the longest period
3 of time that it would take for the symptoms to first
4 appear, to first manifest themselves.

5

A. I think most people would
say between 1-1/2 to 2 hours.

6

7 Q. Thank you. Now, also,
8 if I may turn you to the chart of Kevin Pacsai which
9 is Exhibit 106, and if I can ask you to turn to page
10 65 of that exhibit, Doctor. Could we also have the
Inwood chart, Mr. Registrar?

11

12

A. Is that page 65 of the Pacsai
chart?

13

14

15

Q. Yes. If I can draw you
to the entry from between 3:45 and 6 a.m. of March
12th, 1981, in particular, and the entry related to
4:00 in the morning:

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"Nutrition; at approximately 4 a.m.
attempted to feed baby and his
behavior was entirely different from
other times. He was lethargic and
limp in my arms."

Would you agree with me, Doctor, that that would be
the best possible evidence of digoxin toxicity, if
there was a lethal dose administered in this case?

A. I take it the poor feeding,



1

2 this is a general description?

3 Q. Yes. You see, the apex was
4 found to be very irregular.

5 A. Okay.

6 Now, going on with the rest
7 of that description, I think that is very compatible
8 with intoxication, clinical presentation of it, yes.

9 Q. So when Doctor, we talked
10 about, at the inception we talked about one adult vial,
11 if you were to take a multiple vial situation would
12 the time frame for manifestation of the symptoms
accelerate?

13 A. I'm not sure I understand
your question. Does that mean if --

14 Q. Let me posit it this way.
15 If you had a multiple vial administration would the
16 symptoms appear earlier than they would with the
17 one vial situation?

18 A. By multiple vial you mean the
contents of -- that is a large amount of drug.

19 Q. A large amount of drug.

20 A. Okay, correct. Yes, I think
21 that one would expect that the onset of symptoms
22 would be hastened.

23 Q. That is they would demonstrate

24

25



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2 themselves earlier than they would with a smaller
3 dose?

4 A. Yes.

5 Q. And so that going back there,
6 the first evidence, possible evidence of digoxin
7 toxicity, would you agree with me, Doctor, that the
8 earliest that a lethal dose of any one vial could
9 have been administered to this child would have
occurred at approximately 2 a.m. in the morning?

10 A. Now, that presumes of course,
11 oral route.

12 Q. That is either oral or
13 intravenous.

14 A. Well I think we probably
should lump both the oral and intravenous together.

15 THE COMMISSIONER: The earliest,
16 I think, would have to be 2:00, isn't that right,
17 because the earliest for the IV, I think is somewhere
18 close to 3:30; and the earliest of the IV --

19 THE WITNESS: The oral.

20 THE COMMISSIONER: Of the oral, I
am sorry, will be 2:00, so the earliest I think would
21 be 2:00.

22 THE WITNESS: Okay, that question,
now I see it, it is satisfactory, I understand it.

23

24

25



1

2 Q. All right.

3

4 A. So I think then I would agree
5 going back roughly two hours, or to an hour and a
half from 3:45.

6

Q. To 4:00.

7

A. Oh, from 4:00, or 3:45?

8

Q. 4:00.

9

A. I have in here 0345.

10

Q. "Approximately 0400 attempted
11 to feed babe and his behavior was
entirely different..."

12

13

A. Okay. That is the time you are
using?

14

Q. Yes.

15

A. You go back to 2:00, you

are suggesting?

16

Q. I'm suggesting the earliest
possible time at which the lethal dose of digoxin
could have been administered on this child.

17

18 A. I think that is an acceptable
interpretation, yes.

19

20 Q. So that if my client had left
the hospital at 7:30 the evening before it is very
21 clear that she could not have had any direct involve-
22 ment in the death of this child in terms of digoxin
23

24

25



1

2 toxicity?

3

A. I would accept that.

4

O. Let's then move on to the
Inwood chart which is Exhibit 113. If you can assist
me by turning to page 63 of that chart, Doctor.
If you have a look at that notation, Doctor, you will
see that at 0200:

5

"Babe was feeding poorly all night,
fed by NG tube."

6

Would that be a nasal gastric tube?

7

A. I presume it would be.

8

O. All right. Apex 152 to 119
and respirations down and then lasix was given; and
you will see further down 0200 monitor strip showed
abnormalities, team leader notified. Then at 2:30
a code 25 is called for resuscitation.

9

10

Would you agree with me, Doctor,
that if there was digoxin toxicity in this case that
the symptoms first seem to have manifested themselves
at 2:00 in the morning?

11

A. That seems to be so.

12

THE COMMISSIONER: Well, I'm sorry,

13

I disagree:

14

"Was feeding poorly all night..."

15

Does that not mean that the child, the first symptoms

16

17



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2 could have been earlier?

3 MR. OLAH: Well, sir, I guess maybe
4 we should focus on the apex dropping, respiration
5 dropping and the abnormalities being shown on the
6 monitor strip which is the --

7 THE COMMISSIONER: Well, maybe you
8 are right, certainly I want the expert to give the
9 evidence, not me. Feeding poorly all night, poor
10 feeding would conceivably be, could that not be a
symptom of digoxin intoxication?

11 THE WITNESS: Yes, it could be --

12 THE COMMISSIONER: A symptom of
something quite different.

13 THE WITNESS: Of heart failure and of
14 the disease process itself. So it is a pretty soft
15 sign and I am not prepared to accept that as the basis
16 of digitalis intoxication alone. I think though that
17 at this point this is the first evidence that we have
18 of an arrhythmia, at least as noted on the monitor
19 strip, is that correct?

20 Q. That would seem to be the
case, Doctor, if you could turn back to page 62.

21 A. Yes.

22 Q. You will see that an entry
23 for 12.3.81, cardiac apex 122 to 155 regular; respiration

24

25



1

2 98 to 58; his blood pressure; his nutrition, will
3 not drink -- I'm sorry, nutrition, will not drink from
4 bottle, that is what it says, but it seems to be that
5 there is a continuing problem with feeding but the vital
6 signs seem to be stable early in the day.

7

A. Yes.

8

Q. So that the first time we have
9 any arrhythmias being demonstrated are at 2:00 in the
10 morning and there seems to be some concern because
11 the team leader is notified and the resident is called
12 at 2:00 in the morning, and we have got the dropping
of the apex and the respirations.

13

A. Well, you are not going to
14 use a decrease of respiration as a sign of digitalis
15 intoxication, or are you?

16

Q. Well, I don't know, I don't
17 know if we have to get into the individual signs.
18 What I want to know, Doctor is, do you see any evidence
19 of digitalis toxicity prior to 2:00 in the morning of
March 13th?

20

THE COMMISSIONER: Again that could
21 be digoxin intoxication, is that what you mean?
I'm sorry, you said do you see any evidence of digoxin
22 intoxication.

23

MR. OLAH: I would like the question to

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25



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2 be anything that could be, anything that could be
3 sure.

4

THE COMMISSIONER: Yes, all right.

5

6 A. I think that we have to
conclude that this dramatic change occurred on the
13th.

7

8 MR. BROWN: Just on this point, Mr.
Commissioner, page 89 of the medical record which I
9 believe is page 8 of the flow sheet indicates the
10 pulses. Now, I have photocopied it and I don't
11 know what the times are in the left hand margin, but
12 there are a number of notations there as to the
13 pulses at various times.

14

15 THE WITNESS: Yes. Well, they do, if
one looks at this they do look fairly stable up until
16 the end, aren't they, they go from 128, mostly in the
range of 130 or so, some 150. I wouldn't have
17 interpreted from the heart rate at least that this
18 patient was experiencing evidence compatible with
19 intoxication until the events, the terminal or the
20 events on the 13th.

21

THE COMMISSIONER: Is that at 2:00

22

in the morning?

23

THE WITNESS: Yes. If you look at
page 62 we see it says:

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2 "Code 25 called."

3 The third entry down, do you see that on page 62,
4 it says: "Number 25 call."

5 Q. Two-thirds of the way down?

6 A. Two-thirds, yes, the date
is unclear, is that also --

7 Q. That is the entry by the
8 fellow on call, Dr. Mounstephen who responded to
9 the code 25 that we see noted on page 63.

10 All right, that is the
11 arrest.

12 A. Okay.

13 Q. You will see that at 0230
14 hours that is 2:30 in the morning the code 25 was
15 called and that is Dr. Mounstephen's note as to the--

16 THE COMMISSIONER: Yes, but I think
17 the date is what he is having trouble with, that
18 is -- that has to be the 12th, does it not?

19 MR. OLAH: If she died on the morning
20 of the 13th.

21 THE COMMISSIONER: Following the date
22 of death is given in Dr. Mirkin's report as the 12th,
23 you say it is the 13th, is it?

24 MR. OLAH: Yes, the early hours of
25 the 13th.



1

2 THE WITNESS: I have 13 in my
3 report here as the date of death.

4 THE COMMISSIONER: Oh, I am looking
5 at the wrong chart.

6 THE WITNESS: I think I would have
7 to agree with what counsel is suggesting, that the
8 primary evidence we have is that this child showed
9 evidence of digitalis intoxication on the 13th at
10 the time 0200 and it is also reassuring to know that
the monitor strip showed some abnormalities.

11 THE COMMISSIONER: Isn't that what
12 Ms. McIntyre was asking about whether a nurse could
determine from that --

13 THE WITNESS: I think someone brought
14 this up earlier in the morning, I think so.

15 THE COMMISSIONER: That is a similar ques-
16 tion that you were asked, whether a nurse could
17 determine from the monitor the irregularity of the
18 heart which might indicate digoxin intoxication.

19 THE WITNESS: I think it may,
20 apparently in this particular case they did.

21 THE COMMISSIONER: I'm sorry, I didn't
22 know who it was, I think Mr. Knazan asked that, he
23 did ask with respect to a nursing assistant, does
that make any difference to you, a nursing assistant

24

25



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2 or a nurse being able to do it?

3 THE WITNESS: No.

4 THE COMMISSIONER: In your hospital
5 do you have that class distinction?

6 THE WITNESS: Well, we have class
7 distinctions in our society, I think they also extend
8 into the profession.

9 THE COMMISSIONER: There are judges,
10 for instance, of high standing and there are
11 commissioners of low standing.

12 MR. OLAH: You should know that this
13 commissioner happens to be a judge of the Court of
Appeal, which is a high standing.

14 THE COMMISSIONER: Was.

15 MR. OLAH: On temporary leave of
absence.

16 Q. Going back to my question,
17 Doctor, it is your opinion that if there is digoxin
18 toxicity involved in the death of this child that
19 the first evidence or symptoms of such toxicity
20 manifested themselves at 2:00 in the morning.

21

22

23

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I.1

2 A. Yes, I think we can accept
3 that conclusion.

4 Q. All right. So, going back to
5 the same question I put to you with respect to the
6 Pacsai child, would you agree with me, Doctor, that
7 the very earliest that a lethal dose of digoxin could
8 have been administered to this child would have been,
9 taking back the two hours, would have been midnight
of March 12, 1981?

10 A. Correct.

11 Q. And again if my client were
12 off at 7:30 the evening previously, that is, the
13 evening of March 12, she could have had no direct
14 involvement assuming hypothetically that it is dig.
15 toxicity with the death of this child?

16 A. I would agree with that
conclusion.

17 Q. Thank you. Now, I would like
18 to then turn to the Hines child. That is Exhibit 103,
19 Mr. Registrar. I am going to ask you, Doctor, to
turn to page 68 of that chart.

20 Now, Doctor, again I would like to
21 work on the assumption that digoxin was the cause of
22 death of this child. Assuming that hypothetical, I
23 would like to determine with you when the first

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evidence or symptoms of digoxin toxicity could have manifested themselves prior to the death of this child.

5

6

At page 68 we have an entry with respect to the long night during which the child died. You will see that with respect to the cardiac status, about half way down page 68, apex taken, what is it, every hour?

9

A. Yes.

10

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Q. And 160 to 124 and regular. At 4 o'clock apex up at 182 but was regular and the child seems to have been feeding well. And then if we drop down further down the page, slept between feedings with no distress. Then we have an entry at 4 o'clock, apex 182 regular, respiration 54, no distress, arrested at 4:10.

A. Yes.

Q. Would that suggest to you, working on the hypothesis I put to you, that the first manifestation of digoxin toxicity would have occurred at about 4:10 of that morning?

A. Well, I think we may want to modify that a little bit. If you look at the second entry here under that notation, at 300 the baby vomited. Now, again, if one wants to use emesis as



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an index we might suggest that perhaps that was an early sign at 0300 rather than 0400 but I will just put that into the record that that is a possibility so that if we are going back again two hours it might be at 0100 rather than at 0200 at the very, very earliest perhaps.

(2)

Q. All right. So, to err on the side of caution in this case you say that the earliest time at which a lethal dose of digoxin could have been administered in this case would have been 1 o'clock in the morning?

A. About that.

Q. And again if my client were off at 7:30 in the evening, the evening previously, she could have had no direct involvement in any such digoxin-related death working on that assumption?

A. Correct.

Q. Thank you. I would like to take you then just very quickly through the Lombardo child. That is Exhibit 78, Mr. Registrar. I am going to ask you to turn to page 41 of that record, Doctor.

Mr. Registrar, the next exhibit will be the Belanger charts.

Again, Doctor, I would like to work



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2 on the same hypothesis, namely, let us assume for
3 the purposes of our discussion that digoxin was
4 indeed the cause of death in this case. I would
5 like to establish when in your opinion the first
6 evidence of digoxin, possible digoxin toxicity
7 occurred in this child.

8 THE COMMISSIONER: Lombardo, what page
9 did you say?

10 MR. OLAH: It is page 41, Mr.
Commissioner.

11 Q. If you go down to the bottom
12 of the page, Doctor, maybe I can decipher the chart
13 for you. It is an entry between 1900 hours and 0330
14 hours in the morning. Patient relatively stable.
15 Heparin infusing well, patient feeding eagerly, 1-1/2
16 to 2 ounces - I guess that would be every three
17 hours - apex 144 to 152 and regular, respiration 150
18 to 50 shallow but in no distress.

19 MR. LAMEK: It is 50 to 52.

20 MR. OLAH: Is it 50 to 52?

21 MR. LAMEK: Yes.

22 MR. OLAH: My apologies.

23 Q. 50 to 52. Colour pink in room
air, dusky when upset, became restless after second
feed, however, settled well. Then there is an entry

24

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2 next at 3:30 in the morning. Baby became restless,
3 breathing very shallow, apex irregular and bradycardia,
4 placed on cardiac monitor. Turning over to the next
5 page, colour became more dusky and then oxygen 100
6 per cent given and then there is an entry about
7 vomiting a small amount of mucus and then a Code 25
is called.

8

9 Doctor, what is your opinion as to
when the first evidence of possible digoxin toxicity
10 is demonstrated in this case?

11

12 A. I think the only written
observation is at 0330 and whether it occurred between
13 1900 and 0330 is difficult to say but I am assuming
that had anything occurred in that interval it would
14 have been recorded.

15

16 Q. That is the practice at the
Hospital as we understand it?

17

18 A. Yes. So, I think we have to
accept the 3:30 a.m. report as a time at which we are
19 seeing some problems and let's say we would work
from that time frame.

20

21 Q. And again we apply the two-
hour time frame we discussed earlier?

22

A. Correct.

23

Q. All right. If I can then move

24

25



I.6

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2 to the last child I would like to discuss with you
3 in terms of time, and that is the Belanger child, and
4 I would like you to turn to page 64, Doctor, of the
5 medical chart. I would like to direct your attention
6 to the top of page 64. You will see that is an
7 entry between 1 o'clock in the afternoon and 7 o'clock
8 in the evening. Stable during the afternoon, apex
9 134 to 170 and regular and he is tube-fed, suctioned
10 for moderate amount of white mucus, colour remained
11 pink and there is an entry at 6:30 in the evening
12 that apex was noted to be regular, colour somewhat
13 dusky, respiration up to 80 and very shallow, detube
14 feeding and progress, suctioned orally for moderate
15 amount of white mucus, colour extremely poor, doctor
16 notified and present, apex dropped and cardiac arrest
17 called.

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Doctor, what is your opinion as to,
assuming that digoxin played a role in this child's
death, the first evidence or manifestation of possible
digoxin toxicity?

A.

It looks like it is at about
1830 when that occurred.

Q.

And again to determine the
earliest possible time for administration of a lethal
dose of digoxin, assuming digoxin played a role in



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2 this death, we take your two-hour time interval?

3

A That is correct.

4

5

Q Thank you. Doctor, I would like to then turn you to the child Laura Woodcock if I may.

6

THE COMMISSIONER: I don't think you need to bother too much about Woodcock, your client was not employed at the time, was she?

7

MR. OLAH: Pardon me?

8

9

THE COMMISSIONER: I am sorry, I shouldn't anticipate.

10

11

MR. OLAH: That's the point, precisely.

12

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THE COMMISSIONER: Well, I know that. If you wanted to make sure that the doctor knows that too, that's fine.

14

15

MR. OLAH: Oh, no, no, I wanted to ask about the condition of the child. It is in my interest to determine the level of probability because if ---

16

17

THE COMMISSIONER: I don't want to argue, just go right ahead.

18

19

MR. OLAH: I will just be very brief.

20

21

THE COMMISSIONER: Okay.

22

23

MR. OLAH: Q. Doctor, would you agree

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2 with me that the severity of the cardiac lesion
3 with respect to this child is probably one of the
4 lowest of the 36 that you reviewed?

5 A. Yes, I think so.

6 Q. And that if you were to put
7 Laura Woodcock on some sort of a range, as Mr. Lamek
8 has done in terms of severity of cardiac status, where
9 would you rate her on a scale of 1 to 10; 1 being the
least severe, 10 being the most severe?

10 A. Oh, probably close to 1, 1.5,
11 low down.

12 Q. And if you were to take into
13 account her jaundice and her poor feeding and rate her
14 in terms of danger, a life threatening situation,
where would you rate her on a range of 0 to 10?

15 A. I guess one of the problems
16 in assigning that rating now was the difficulty in
17 knowing just what the cause of the jaundice actually
18 was. If for example the jaundice was attributable
19 to intrahepatic biliary atresia as an example, that
means they would have to come up to Minnesota and get
20 a liver transplant, the odds of survival would be
21 relatively low.

22 So, if you asked me based on the
23 jaundice I would have to really determine what was the
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cause of the jaundice, was it infectious hepatitis, was it some fundamental anatomical problem in the patient? I don't know what the diagnosis on that actually was. We have jaundice severe with a questionable etiology. I raise that more to attempt to indicate that the mere presence of jaundice or the presence of jaundice is not necessarily a trivial or not life threatening problem. That is the only reason I bring it up.

10

11

12

Q. I understand that, Doctor. Did you have a chance to look at the final autopsy report relating to this child?

13

14

15

16

17

18

19

20

21

A. I have here three items. I

can recite them to you. One, it says expected cholestasis, that is a jaundiced child. I didn't see a histological analysis of the liver, perhaps we missed it. The second post mortem finding was bilateral pneumonia, the third, there was some degeneration of an area in the brain. I don't have Woodcock's chart here but I am reciting from our summary of the chart. Is there a pathologist's report on that?

22

Q. Yes. Exhibit 117, please,

Mr. Registrar.

23

A. If the pathologist's report

24

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2 indicates a relatively benign cause for the jaundice
3 then I would be able to assign a low number to that.

4

5 Q If you look at page 30,
6 Doctor, and I'm not sure I can tell you whether it
is a benign cause or not and maybe you can help us.
7 If you'll have a look at paragraph 4.

8

9 A I see it. Cholestasis, that
10 is the accumulation of bile with severe enlargement
11 of the liver and plugging of bile. It doesn't say
anything about the etiology, nor does it say anything
about the histological findings on that.

12

13 Q The only additional information
we have is at page 33.

14

15 A Yes, I am looking at that
right now, thank you.

16

17 Q And the biliary tree appears
to have been patent.

18

A Was what, patent?

19

Q Yes.

20

21 A Good, okay. I think what one
could conclude from the findings on page 33, is that
there was no anatomical anomaly in the liver in that
this baby had jaundice of an unknown cause and I think
I would conclude this is a baby at sort of real modest
risk of death in this acute form at this stage in
his life.

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Q. All right. So, going back
to the scale, taking the total clinical picture,
where would you rate her in terms of jeopardy of
death as a result of her clinical status?



Mirkin
cr. ex. (Olah)

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2 A. I think about two, on the
3 low side.

4 Q. Doctor, did you have a chance
5 to review this chart at all as to the progress of the
6 child while she was in the hospital?

7 A. Only in the sense that we
8 reviewed this patient during our team meeting, and
9 I have a summary of her chart in front of me.

10 Q. Would you agree with me that
11 until June 30th, 1980, her course in the hospital
12 was fairly uneventful?

13 A. Yes, I think that is ac-
14 ceptable. There was, though, a notation I have, and
15 you can check this, on June 26th she was having
16 some feeding problems. She had rapid respiration
17 and of course she had this enlarged liver and she had
18 an elevated bilirubin. Overall, I think we had
19 the impression that there was nothing that would be
20 considered life threatening in the history of this
21 patient up until June 30th.

22 Q. Would you agree with me,
23 Doctor, that in fact there was a dramatic change in
24 her condition on June 30th of that year?

25 A. I think I would agree.

O. And certainly I believe that



1

2 was something that was unexpected, in your opinion.

3

A. Yes, I think these events were
4 unexpected.

5

Q. Because she is one of the
6 children whose death you have noted as being un-
7 anticipated.

8

A. That is correct.

9

Q. I think you indicated that
10 your index of suspicion with respect to digoxin
11 playing a possible role was seven out of ten?

12

A. That is not Laura
13 Woodcock, is it?

14

THE COMMISSIONER: I think so.

15

MR. OLAH: I would be glad to read
16 your evidence in that regard, two days ago, if you
17 like, Doctor, if it will assist you. At page 8965:

18

"I would kind of put this up about
19 on my scale seven out of ten."

20

A. Was that based on the subse-
21 quent information that we received about here?

22

Q. Let me take you back to the
23 question that Mr. Lamek put to you.

24

A. Please.

25

THE COMMISSIONER: What is that
page number again?



1

2 MR. OLAH: Page 8965, volume 87.

3 Q. Perhaps we should start at
4 page 8964 where you reviewed the child's medical
5 condition and then turning to the top of page 8965
6 you said this:

7 "We concluded that we could not find
8 any obvious cause for the very rapid
9 progression of this patient's problem
10 and concluded that this was an un-
11 expected death."

12 Then the question arose from that:

13 "Q. An expression that we have
14 heard from time to time in the course
15 of these proceedings, Dr. Mirkin, is
16 'index of suspicion.'

17 Could you give us some indication
18 of the index of suspicion that you have
19 with respect to this child?

20 A. I would kind of put this up
21 above, in my scale, 7 out of the 10."

22 A. I think this is one of
23 the patients where I modified our original scoring
24 based on the discussions the other day. Yes, okay,
25 that is perfectly correct.

26 Q. How does that relate, Doctor,



1

2 in terms of your index of suspicion with respect
3 to the children, Cook, Miller and Pacsai?

4 You remember that these three children were your
5 category one type death.

6 A. Those were children who we
7 found relative -- we had toxicologic evidence
8 to determine the presence of digoxin. Is that
9 correct?

10 Q. That is correct, Doctor.
11 You term them as probable.

12 A. What is it that you are asking
13 me?

14 Q. I guess what I am trying to
15 determine is whether you feel that Laura Woodcock
16 now falls into that category of death or whether
17 she falls somewhere below that category.

18 A. We have no confirmation --
19 no toxicologic calculation in Laura Woodcock.

20 Q. Actually, there is some
21 minimal toxicology and maybe I should direct you to --

22 THE COMMISSIONER: You can do it,
23 if you like but I think he has given his evidence
24 several times that he cannot rely on that. She had
25 been receiving digoxin.

26 MR. OLAH: At the referring hospital.



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THE COMMISSIONER: Yes. And this
was exhumation ---

4

5

MR. OLAH: Yes, sir, and there was
very minimal toxicological data which was probably
neutral.

6

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THE COMMISSIONER: Well, you can refer it
to him, if you like, but I know what the answer is
going to be, that he cannot rely on that for
confirmation of --

10

11

MR. OLAH: I realize that. I think
in all fairness he should have all of the evidence --

12

13

14

THE COMMISSIONER: All right, I
should learn, I should be quiet and I am going to be
quiet, I promise you. Carry on. Sometimes even the
old never learn.

15

16

17

MR. OLAH: I think what it is is
your ample and best experience in the courts and
young counsel sometimes --

18

19

THE COMMISSIONER: Carry on. Put
the question.

20

21

22

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Q. Doctor, I should put something
to you that you may not be aware of. Could I have
Exhibit 95-E, please, Mr. Registrar? I would like
to refer you to page 5 of Exhibit 95-E. You will
see that sample T103- is a sample from the exhumed



1

2 autopsy of Laura Woodcock and it is a sample of tissue
3 in a jar marked muscle and there was a trace of a
4 digoxin like substance, 4 nanograms per gram,
5 calculated digoxin indicated. Have you ever seen
6 this report before, Doctor?

7

A. I have been told it was sent
8 to me. I have an earlier one and I think that data
9 was contained in it. Yes, I am sure it was.

10

Q. The other piece of informa-
11 tion that you should be aware of was that while this
12 child does not appear to have received digoxin at the
13 Hospital for Sick Children, that she was digitalized
14 at the referring hospital. Are you aware of that,
15 Doctor?

16

A. I am not sure that that
17 was in our notes. I can check that out in a moment.
18 We have no record that digoxin was given. Was that in
19 the patient's file?

20

THE COMMISSIONER: I think there was
21 a record that she had digoxin at the referring
22 hospital.

23

Q. If I can turn you to page
24 38 of the hospital chart, Doctor, you will see about
25 two-thirds of the way down the page:

"Seen in Oshawa. Large heart on



1

2 X-ray, digitalized, some improvement."

3

A. Okay.

4

Q. You will see underneath

5

that:

6

"Last night heart rate 40, dig.
discontinued."

7

A. Okay. I think that may not
have been picked up by the reviewer. We have in our
interpretation assumed this patient received no
digitalis in the Children's Hospital, I think that
is correct.

12

Q. That is correct. Now, does
the minimal data that you have got in terms of
forensic data, does that have any impact upon your
opinion whatsoever?

15

A. No, I don't think that is
much help to me.

17

Q. So then, just going back to
the question that I was trying to deal --

19

A. Could I qualify that a bit?

20

Q. Yes, please do.

21

A. This was exhumed data taken
how long after --

22

Q. A minimum of 18 months,
Doctor.

24

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A. That is very difficult to

3 interpret. I think I would probably just let it be.

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Q. Going back to the question

that I posed to you earlier, where would you rank

Laura Woodcock in terms of the category 1 children,

namely, Cook, Miller and Pacsai?

A. I think they have to be

ranked with lesser certainty because of the lack of

toxicologic data, and my change in the rating

here, as I look upon this very acute course of

events that occurred in this patient, in our

original scoring we had a zero. You can see that.

Q. Yes.

A. I think this change to seven

was based on my review here. I think it is a scenario

very compatible with dig. intoxication as well and

we just did not have any electrocardiographic

data to confirm the view; we had not toxicological

data. We eliminated the possibility that this patient

could be dig. intoxicated because by record she had

not been given any digitalis.

If one eliminates the last

possibility, let us say, and examines the actual

findings in this patient, I think it becomes apparent

that the clinical presentation here between the hours



1

2 of 3:00 to 9:30 at night are very compatible with
3 dig. intoxication. I would put them at a lesser
4 order of certainty than the first three because of
5 the absence of toxicological proof. That is the
basis for that designation.

6

7 Q. But it is still in your view
8 a fairly high probability that digoxin played a rôle
9 in this child's death?

10

11 A. Yes, I think that the ranking
12 of 7 that I reassigned to it would suggest that.

13

14 Q. A final question before I
15 sit down, Doctor, relates to the child David Taylor
16 and you will recall that when you were examined by
17 Mr. Lamek your opinion at page 8843 was that there was
18 a clear connection between digoxin and the child's
19 death. The question I want to put to you, Doctor,
20 was, applying Mr. Lamek's index of suspicion, where
21 would you put David Taylor?

22

23 A. I think we thought that

24

25 David Taylor had a very high likelihood of digitalis
intoxication and the index of suspicion that Mr. Lamek
uses for what, now?

26

27 Q. You gave him a rating of 9,
28 but what I want to know is in your opinion what
29 probability, in terms of the index of suspicion,

30

31



1

2 zero to ten--

3 THE COMMISSIONER: And you want to
4 go further than that. Do you want to say as the
5 cause of death?

6 MR. OLAH: Precisely.

7 THE COMMISSIONER: As opposed to
8 just being toxic during life.

9 THE WITNESS: I think that is the
10 point and I think I would rate that very high, in the
order of 9.

11 THE COMMISSIONER: That is as the
12 cause of death?

13 THE WITNESS: As the cause of death,
yes.

14 MR. OLAH: Q. Just out of curiosity,
15 Doctor, what would you rate Justin Cook at?

16 A. Justin Cook. I would rate
17 him a very high also.

18 Q. Would it be a 9 or a 10?

19 A. I really am not able to
20 engage in discrimination in that. I think it is very
21 important to say a high level of suspicion in my
mind.

22 MR. OLAH: Thank you, Doctor. I am
23 very grateful for your assistance.

24

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2 THE COMMISSIONER: Mr. Labow?

3 MR. LABOW: Thank you, Mr. Commissioner.

4 CROSS-EXAMINATION BY MR. LABOW:

5 Q. Good morning, Dr. Mirkin, my
6 name is Stephen Labow and we represent six sets of
7 parents whose children died in this matter.

8 Doctor, I already told you that I
9 would be referring to an article that you co-authored,
10 that you told me you had a copy of and it is called:
11 "Kinetics of Digoxin Absorption and Relation of Serum
12 Levels to Cardiac Arrhythmias in Children".

13 THE COMMISSIONER: Is this your
14 article, I take it it is?

15 THE WITNESS: I think I did, I will --
16 yes, that is mine.

17 THE COMMISSIONER: I know, but I just
18 want to make sure it is.

19 THE WITNESS: That is mine, thank you.

20 THE COMMISSIONER: Exhibit 317.

21 ---- EXHIBIT NO. 317: Article entitled: "Kinetics
22 of Digoxin Absorption and
23 Relation of Serum Levels to
24 Cardiac Arrhythmias in
25 Children".

26 MR. LABOW: Q. Doctor, this was a
27 study of 15 children with congenital heart defects,
28 my understanding?



K.2

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2 A. I beg your pardon, I am sorry.

3

Q. This was a study of 15 children
4 with congenital heart defects?

5

A. That is correct.

6

Q. All of whom were receiving
7 digoxin?

8

A. Yes.

9 Q. And I would like to turn to your
10 conclusions and your discussion at page 394. At the
top of the second column you point out:

11 "Despite a significant increment in
12 the serum digoxin concentration, there
13 appeared to be no evidence of an
14 increased tendency towards electro-
15 cardiographic abnormalities or
16 clinically discernible toxicity ... "

17 My reading of your article seems to
18 indicate that your overall conclusion was that you
19 really couldn't rely upon any relationship between
20 rising serum levels and the appearance of cardiac
arrhythmias?

21 A. I think that is not an
unreasonable conclusion to draw from that. What we
22 really were attempting to get out was the variability
23 in reaching a judgment, the problems in reaching a

24

25



K.3

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2 judgment solely from the level itself, as the
3 predictive value of such information left much to
4 be desired, I think that was the issue.

5 Q. At the very bottom of that
6 column just starting: "The data obtained ...".

7 A. Yes.

8 Q. You discussed the idea that:

9 "There was no clear relationship ...
10 reliance solely on serum concentrations
11 ...will prove misleading in a very
12 large percentage of cases."

13 A. That was our opinion in 1971.

14 Q. Is that still your opinion?

15 A. I think that in children that --

THE COMMISSIONER: I am sorry, did you
16 say 1971?

17 MR. LABOW: Q. This is dated 1974.

18 A. Oh, 1974, well, okay.

19 THE COMMISSIONER: 1971 I think was
20 the first, wasn't it, the first digoxin levels taken
21 in 1971, am I wrong, perhaps I am wrong?

22 THE WITNESS: I think some early
23 articles were done.

24 THE COMMISSIONER: I thought the first
25 time they were able to take the levels at all was 1971,
am I wrong?



K.4

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THE WITNESS: You mean the radioimmuno-assay?

4

THE COMMISSIONER: Yes.

5

THE WITNESS: It is probably around that time, I think that is correct. Excuse me, I am sorry.

7

MR. LABOW: Q Now, is it still your opinion --

8

MR. LAMEK: I suspect, Mr. Commissioner, that Dr. Mirkin is right, on the first page, page 387, it is recorded:

11

"A preliminary report of this investigation was presented to the Society for Paediatric Research, April 24, 1971."

14

Indeed the work may have been done at that time.

16

THE WITNESS: God, time flies.

17

MR. LAMEK: A great memory though.

18

THE COMMISSIONER: They received it for publication July 13th, 1973. So obviously, I guess if they received it for publication you are not allowed, or are you allowed to amend it after that date?

21

THE WITNESS: Oh, it was received for publication and then we probably made some editorial modifications.

24

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K.5

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THE COMMISSIONER: But not any changes
in substance?

4

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THE WITNESS: No, this is the final
paper.

6

MR. LABOW: Q. Is this still your
opinion today, Doctor?

7

A. That the --

8

Q. That reliance on serum
concentrations will prove misleading in a great
number of cases?

9

A. Alone, yes, I think so.

10

Q. Does that work both ways? In
other words, is it true that a child could be
intoxicated with a low concentration and at the same
time another child may not be intoxicated with a
relatively high concentration?

11

A. It is a difficult question to
answer, but I think that certainly that is possible.
You know, one way of looking at it is that if you
consider that the human being, unlike an inbred
animal has a normal distribution of response, so that
there are individuals who respond to low doses and
some to high. So based on that presumption and that
actual fact I think in practice, the answer to your
question must be, yes.

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K.6

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Q. Now my last comment on this paper is that at the bottom of the column, the last paragraph on page 395 in the left column, you say:

(2)

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8

"It is noteworthy that transient, but dramatic increments in serum digoxin levels following acute poisoning in infants may occur with minimal signs of clinical intoxication."

9

10

11

12

13

A. Yes, we experienced that and the explanation for that still sort of is obscure to me. I think it is important to recognize though that these children had normal hearts I think if my recollection is accurate.

14

Q. The children you studied in this?

15

A. No, these two.

16

Q. These two children?

17

A. These are children that I

18

anotated on page 395, and my recollection is that they somehow became intoxicated by getting into a parents' supply or something of that sort, and they were normal. We found I think - although I don't swear to this, that there have been other reports of acute ingestions, single doses, where the abnormalities produced by these very high concentrations have been minimal and that is still I think a valid observation.

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K. 7

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Q. Now would you, or could you go
as far, based upon the idea that these children were -
had structurally normal hearts, for our situation
where most of the children did not have structurally
normal hearts, could the same thing happen?

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A. I guess it could happen but one
must be concerned about the varying response or
differential response of the sick heart so to speak
and the abnormal heart to the drug. It has been
suggested I am sure by many of your consultants that
the pathological heart may have a different sensitivity
to the digoxin than the normal. So I think we have
to qualify that and not make it a complete
extrapolation from normal to a pathological situation.

THE COMMISSIONER: A different one,

generally speaking, would make more sense, wouldn't it?
I was leading you there.

THE WITNESS: That's fine. That

is difficult to say, there are some situations where
a pathological heart does not seem to respond,
digoxin does not produce a beneficial result and one
could say that the heart is less sensitive. On the
other hand there are patients with abnormalities of
the heart where you get very toxic events at low
doses.



K.8

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THE COMMISSIONER: There are certainly some, and I would say those are probably the cases of Cook, Lombardo, Hines and Belanger, where a suspicion that they may be too sensitive to digoxin, that digoxin toxicity would be reached apparently with the first dose. Isn't that --

THE WITNESS: Well, I think there are some patients where the pathology would enhance their sensitivity. I think the answer to your question is yes.

MR. LABOW: Q. Now Doctor, do you still have Kristin Inwood's medical chart?

A. I do not.

MR. LABOW: Mr. Registrar, I will be referring to the Gionas child's chart as well.

THE WITNESS: Which one are we doing now?

MR. LABOW: Q. Inwood, No. 32, your code.

Mr. Commissioner, just to clarify one of the problems this morning, it is my understanding with Kristin Inwood that when she entered the Hospital for Sick Children, when she was transferred, digoxin was prescribed but because the electrocardiogram showed some abnormalities it wasn't ordered held but none of the digoxin was administered. On page 87 of the chart you can see in the medication record that



K.9

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2 there was no digoxin signed off for those first
3 doses and then it is ordered held.

4 THE COMMISSIONER: Is this a record
5 from her admission on; this is a complete record
6 from her admission on, is it?

7 MR. LABOW: The information I just gave
8 you I got from Dr. Bain and Dr. Rowe when I -- Dr.
9 Bain especially when I asked him because we really
10 were not sure why no digoxin was administered at the
beginning.

11 THE COMMISSIONER: Did she - I am sorry,
12 confusion reigns supreme today certainly on Kristin
13 Inwood. Was she digitalized in some other hospital?

14 MR. LABOW: She was receiving digoxin
15 at the other hospital before she was transferred. At
16 Volume 18, page 3087, Dr. Rowe testified that Kristin
17 Inwood had been on digoxin since the 28th of February
18 and she was transferred on the 11th of March and she
19 was not supposed to receive any from that time
forward.

20 THE WITNESS: That would agree with my
notation.

21 MR. LABOW: Q. Now, she did receive
22 that dose in error.

23 THE COMMISSIONER: Is that because a

24

25



K.10

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2 hold order was given?

3 MR. LABOW: Excuse me?

4 THE COMMISSIONER: Was it because --

5 MR. LABOW: Apparently it was because
6 the electrocardiogram showed signs of toxicity, the
electrocardiogram that was taken on admission.

7 Q. Now, Doctor, you told Ms.
8 McIntyre today that in regard to the serum sample that
9 registered a 491 concentration you wouldn't think
10 that there would be any problems, any major problems
11 with it, but you did comment about boiling. Now,
12 could you tell me what boiling would do to the sample
13 to make that reading unreliable?

14 A. Well, I am really not sure at
what temperature digoxin would break down. But if
boiling were of significant duration one could foresee
that the structure of the digoxin would break down
and perhaps be converted to any molecular material
that was not measurable by liquid in the assay systems
that are used.

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Q. Would that raise the digoxin
concentration?

4

A. That would decrease it.

5

Q. Okay.

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THE COMMISSIONER: You said it would
raise it?

7

THE WITNESS: No, it would decrease it.

8

THE COMMISSIONER: Oh, it would
decrease.

10

THE WITNESS: Now, I guess I ought to
give you -- I am looking to see if I have some informa-
tion on the stability of digoxin under those condi-
tions, but I do not.

13

THE COMMISSIONER: Would the boiling
not also decrease some of the fluid as well?

15

THE WITNESS: That's a good point,
yes, it would.

17

THE COMMISSIONER: It wouldn't
necessarily decrease. It would break down the digoxin
and also evaporate the fluid.

20

THE WITNESS: Well, an interesting
thought has just been raised. If you boiled the
material - I am sorry to introduce this. If you
boil the material the Commissioner has suggested that
perhaps some of the fluid might evaporate off so that

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BM/PS



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2 you would have a reduction in concentration actually
3 of the remaining digoxin present. The boiling is
4 a very -- I can't imagine -- pardon me?

5 MR. LAMEK: I thought you would have
6 increased concentration of what was left.

7 THE WITNESS: Exactly, increased
concentration.

8 MR. LAMEK: You said reduced.

9 THE WITNESS: I'm sorry?

10 MR. LAMEK: You said reduced.

11 THE WITNESS: Oh, fine, I will correct
12 that. You have an increased concentration of what
13 had not been actually destroyed by the heating
14 process itself. But I can't really honestly visualize
15 the sample being cooked in a laboratory.

16 Q. Well, I will put it to you that
17 Mr. Cimbura simulated some experiments on heating.

18 A. Yes.

19 Q. And found no significant
change in the levels of digoxin.

20 A. Oh, okay.

21 Q. He has given that evidence
before the Commission.

22 A. Oh, good.

23 Q. But that didn't include boiling,

24

25



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2 as far as I knew and I just wanted to know if you had
3 any background articles that you could refer us to.

4 A. No, I just raise it and I
5 really would have to check on the stability of
6 the drug under those conditions and I think that is
7 easy to do.

8 Q. Okay. Now, you commented
9 on Kristin Inwood's potassium level of 7.3 and you
10 did indicate that you had read Dr. Kauffman's
report.

11 A. Yes, I did indicate that.

12 Q. Now, in Dr. Kauffman's
13 letter of the 16th of December, 1982, and I am not sure
14 what the exhibit number is, he says that hyperkalemia
15 in the presence of normal renal function is consistent
with digoxin intoxication.

16 A. Hyperkalemia?

17 Q. Hyper.

18 A. Well, what did he document
that statement with?

19 Q. He didn't.

20 A. Okay. Now, let me advise
21 you and the other gentlemen that I have found the
22 article that we published in the New England
23 Journal of Medicine. Since we deal with a realistic

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2 data base here, we have no evidence that the plasma
3 potassium level changes in patients who are receiving
4 digoxin. This paper is notated to cover patients
5 who are considered to be toxic, those who are
6 considered to be non-toxic, etc. I think you can look
7 at this and see what you've got.

8

9 MR. SHINEHOFT: Excuse me, Mr.
Commissioner, perhaps the witness would be kind enough
to give us the reference.

10

THE WITNESS: Sure, I will.

11

12 THE COMMISSIONER: Well, we will get
the document, it will become an exhibit after
13 a while. Is that all right? You see, we make copies
of it.

14

15 THE WITNESS: Oh, yes, of course, it
is my only copy.

16

17 THE COMMISSIONER: Well, we can not
only make copies but we can give you several, the
18 original plus several copies.

19

20 THE WITNESS: Thank you. The paper
is in the New England Journal of Medicine, Volume
21 299, page 501-504, 1978, September 7th edition.
Is that too fast?

22

23 THE COMMISSIONER: No, it's not too
fast for the reporter.

24

25



Mirkin
cr. ex. (Labow)

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2 THE WITNESS: All right. Table 1 is
3 the table I am referring to.

4 THE COMMISSIONER: Yes.

5 THE WITNESS: Okay. I did take
6 exception to that conclusion. I think it is kind of
7 important because what the previous counsel presented
8 was the fact that digoxin is indeed able to exert
9 an effect on potassium in the red cell and he is
10 perfectly correct on that score, it does reduce it.
11 Now, where does that go. The question is can you
12 see an elevation in the serum potassium and in our
13 study we did not and I think it would be very important
14 to bring in other data where perhaps that is demonstrated
15 to occur because if we are to postulate that I think
16 the information, since everyone -- I notice Dr.
17 Hastreiter quoted that statement, I think saying
18 there were hundreds of papers in the literature
19 we ought to get.

20 MR. LABOW: Okay.

21 MR. SHINEHOFT: I think as well, Mr.
22 Commissioner, Dr. Kauffman indicated that there were
23 several articles that have been written and I have
24 written to him for a citation and list of those
25 articles which I have not yet received but if I do
I will certainly provide those to Mr. Lamek.



1

2 THE COMMISSIONER: Yes, all right.

3

At any rate, if it is all right with you, Doctor,
we will make that an exhibit, but not until after
lunch so that we will have copies available at the
time.

4

MR. LABOW: Q. Now, doctor, staying
on the topic of the potassium level.

5

A. Yes.

6

Q. This potassium level was
apparently taken at 2:45 on the morning of the 13th.
Now, in the chemistry report at page 81 of the chart
it seems to indicate that the sample taken and used
for that potassium level was at 2:45.

7

A. 2:45?

8

Q. Now, this child arrested at
2:30.

9

A. Yes.

10

Q. And was only pronounced dead
at 3:00. But we have heard that there was very little
response to the resuscitation.

11

A. Yes.

12

Q. Now, it is my understanding
that potassium rises at death. Could the high level
be accounted for because the child actually died at
2:30, notwithstanding when the child was pronounced

13

14

15



Mirkin
cr. ex. (Labow)

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2 dead?

3 A. I think if the temporal
4 events as you describe them are accepted, I think that
5 one might have seen that. I really do not have any
6 knowledge or experience relating to the rate with
7 which this increment in potassium level might be
8 observed post mortem and perhaps that would be useful
9 information. If you are postulating a 15 minute
10 interval between death and the acquisition of the
sample, as I understand you are, is that correct?

11 Q. Yes.

12 A. During that 15 minutes we
13 must postulate the potassium would go up. I think it
14 is possible but I do not have any data to confirm
that impression.

15 Q. Thank you. Now, you seemed
16 to indicate this morning, and I am really very un-
17 clear, that you were relatively confident that the
18 sample that was tested and produced the 491 level was
19 a sample that you could rely on.

20 A. Okay.

21 Q. Is that accurate?

22 A. This sample was obtained
from what site?

23 Q. Well, my understanding is

24

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2 that it was obtained from the sagittal sinus. That
3 is my understanding, although Dr. Taylor said he
4 normally took it from the inferior vena cava.

5 THE COMMISSIONER: What is the
6 basis of your understanding because it may well be
7 you are right. Is that in Exhibit 95?

8 MR. LAMEK: It is T 46 in Exhibit
9 95-C, sir.

10 THE COMMISSIONER: Which, 95-C?

11 MR. LAMEK: 95-C, page 1, sir. But
12 that is not very informative.

13 THE COMMISSIONER: Blood from
14 autopsy from sagittal sinus is the note I have here,
15 but I don't know if that is right. Is that the
16 same note you have?

17 MR. LABOW: That's the same note
18 I have, Mr. Commissioner, and I apologize. I am not
19 sure where I got it.

20 THE COMMISSIONER: None of us know
21 where we got it. It may be from Dr. Bain's report.
22 If you look at Dr. Bain's report, which is Exhibit
23 48.

24 MR. LABOW: Q. Dr. Bain testified
25 that in the report he received from the CDC, not the
one that we see, but the handwritten report, the



1

2 handwritten document that he received from the people
3 from the Center for Disease Control they told him that
4 the sample was from the sagittal sinus. That's the
5 note I have.

6

7 THE COMMISSIONER: Do you have some-
8 thing?

9

10 MR. OLAH: Yes, on page 44 of
11 Dr. Bain's report he said, about half way down the
12 page:

13

14 "I think it was said to have been
15 blood taken at autopsy from the
16 sagittal sinus."

17

18 THE COMMISSIONER: Yes. Well, there
19 we are, all right.

20

21 THE WITNESS: So, we accept that then
22 as being blood from the sagittal sinus.

23

Q. Yes.

24

25 A. Or if we do, what is my data
base. Is there agreement that this is blood from
the sagittal sinus?

26

27 THE COMMISSIONER: It seems to be the
28 only evidence we have.

29

30 MR. LAMEK: Mr. Commissioner, that
31 is not quite so, with respect, and perhaps Dr.
32 Mirkin could deal with the two options. The other

33

34



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2 candidate, as I recall it, was Dr. Taylor who
3 conducted the autopsy and who drew the sample,
4 he had no specific recollection of drawing this one,
5 he said it was his normal practice to draw blood
6 for these purposes from the inferior vena cava. So,
7 perhaps Dr. Mirkin could address both candidates.

8

THE COMMISSIONER: Well, apparently
you have a choice, then, Doctor, inferior vena cava
or the sagittal sinus.

9

10 THE WITNESS: Okay, let's assume it
11 is blood, and I think that is pretty good.

12

THE COMMISSIONER: Yes.

13

14 THE WITNESS: Okay, and I have no
reason to have lack of confidence in that sample, to
the best of my knowledge. It is a post mortem sample
15 and it is very high and if we were writing the paper
and seeing the patient with that we would assume that
16 the patient with that concentration in the blood
17 would very likely manifest some toxic effects.

18

19

MR. LABOW: Thank you, Doctor.

20

21

MR. OLAH: I am not sure if there
is any significance to this, but the witness talked
about blood in the sample.

22

23

THE COMMISSIONER: Serum.

24

25

MR. LABOW: Serum.



1

2 THE WITNESS: Thank you, I stand
3 corrected, that's a good objection.

4 THE COMMISSIONER: Serum is not whole
5 blood but isn't it sometimes referred to as blood?

6 THE WITNESS: No.

7 THE COMMISSIONER: It isn't, it is
8 quite different. It is a product of blood?

9 THE WITNESS: A component of blood.

10 THE COMMISSIONER: Component of
11 blood, right.

12 MR. LABOW: Q. Now, Doctor, just
13 with regard to that and the storage problems, if any,
14 you previously testified when you were here in June,
15 and this is found in Volume 4, page 588 and 589, that
16 serum and/or plasma specimens were usually fairly
17 stable and that most of them are collected and kept
18 in the cold and assayed subsequently and you don't
19 find any problems with these. Is that still your
20 evidence?

21 A. I think that is correct.

22 Q. I would like to look at your
23 review of Philip Turner.

24 THE COMMISSIONER: I wonder if this
25 would be a good time? Are you going to be very
short on Turner?



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2

MR. LABOW: Very short on Turner.

3

THE COMMISSIONER: All right, well,
let's do it.

4

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MR. LABOW: This is code number 2, it
is found at page 129 of Exhibit 313, Mr. Commissioner.

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12jan84

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I would just like you to turn to
part VIII, which is the fourth page. Could you
explain what the conclusion means:

"Only concern is recurrent hypo-
kalemia, which could exacerbate
digitalis toxicity and presence
of pulmonary disease."

What does the sign of the arrow -
toxicity in brackets mean?

A. That means it tends to
increase the potential effect of the digitalis. As
you are aware, in this particular patient, we had
findings that we felt were not consistent with
digitalis intoxication but were more consistent with
problems relating to the basic disease of the
patient. We had a patient who, again with the
restrictions on interpretation that you already
mentioned, had blood levels that were thought to
be in a normal range. We concluded that this
patient was a low likelihood for digitalis
intoxication.

That material on the bottom, the
terminal part, was meant to indicate that, in a
patient who had demonstrable episodes of decrease in
serum potassium, as you know, this tends to enhance



1
M2 2 the effects of the digitalis. That is why that
3 was put in. These notes are really guides to give
4 the broadest possible interpretation here. We
5 checked the digitalis intoxication "absent" here.
6 Well, what other extenuating circumstances could
7 have come into play? So, we put in all the
8 information so it was there for the people to
interpret as best we could.

9 With a low potassium, one might
10 have had the enhancement of digitalis effect. The
11 patient who has pulmonary disease tends to develop
12 acidosis; that is pH in blood goes down. That also
13 predisposes to digitalis intoxication. These are
14 factors that we were trying to factor into the
whole evaluation.

15 I think that is the best I can
16 say about that.

17 MR. LABOW: This would be a good time
18 to break, Mr. Commissioner.

19 THE COMMISSIONER: Until 2:30 then.
20 --- luncheon recess.

21
22
23
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25



12jan84 2 --- on resuming.

AA

DPrC

3 THE COMMISSIONER: Yes, Mr. Labow.

4 MR. LABOW: Mr. Commissioner, we
5 now have the article that Dr. Mirkin referred to.

6 THE COMMISSIONER: We will make that
7 Exhibit 318.

8 --- EXHIBIT No. 318: Article entitled, "Relation
9 Between Plasma and Red-cell
Electrolyte Concentrations
and Digoxin Levels in Children".

10 MR. LABOW: Q. Doctor, my under-
11 standing of the data sheets that you prepared for
12 each child was that essentially what the team of
13 doctors was looking for was evidence, if you will
14 excuse the expression, of digoxin intoxication
during their stay in hospital.

15 A. That is correct.

16 Q. Could you turn to page 49 of
17 Phillip Turner's hospital record. It should be right
beside you.

18 A. Yes, I am here.

19 Q. In the middle of that page,
20 the top half of that page, the whole note is a note
21 by Dr. Soulioti and in the middle of that page
22 it says:

23 "Dig. - episodes of sinus bradycardia

24

25



1

2 therefore digoxin not always given."

3

4 My only question is: Is that not
5 something that might have indicated that there was
6 some question about toxicity or at least toxic
7 effects during the stay in hospital? I do not see
8 that anywhere in No. 2, which is Phillip Turner.

9

10 A. I think that, taken at
11 face value, the episode of sinus bradycardia might
12 certainly be associated with digitalis intoxication
13 but I don't understand the second line in that entry,
14 "episodes of sinus bradycardia". Do you think that
15 those are three dots in the second line in front of --

16

17 THE COMMISSIONER: I think it is
18 "therefore".

19

20 THE WITNESS: I think that is
21 reasonable. "therefore digitalis not always given."

22

23 Now, does that mean there were
24 points during the hospitalization at which the dosage
25 was not administered? Is that in the record, by the
way?

26

27 MR. LABOW: Q. For this child?

28

29 A. Yes.

30

31 Q. Yes.

32

33 A. So, there were moments when
34 the digoxin was held, in a sense?

35

36



1

2 Q. Yes.

3 A. Here we are. Now I am
4 looking at his record.

5 You are asking me whether that
6 would not have indicated that the physician in
7 charge was concerned with some adverse effect of
8 the digoxin?

9 A. That is correct.

10 A. I think that is reasonable
11 to assume.

12 Q. Is this a child where there
13 was some indication of digitalis intoxication during
14 the stay in the Hospital?

15 A. I think the problem that
16 we face with this particular patient is whether or
17 not that particular incident was of such importance
18 or magnitude as to strongly suggest digitalis
19 intoxication. It is my feeling that we felt this
20 particular patient had a type of disease that might
21 have been associated with changes in rhythm. Furthermore,
22 we also, using the data of the blood levels or
23 serum levels, concluded that there was no pharmacologic
24 or toxicologic reason to think that digitalis
25 intoxication was present.

I think that is how we came up with



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2 this very low score.

3 It is important to remember that,
4 at the time that we observed this effect -- this
5 note you referred me to was written on 7-30; is that
6 correct?

7 Q. That is correct. The child
died two days later.

8 A. At that time, according to
9 my records, we had a digitalis level of 0.5.

10 Q. That is correct.

11 A. One of the points that we
12 made, even though the patient had a very low digoxin
13 level, the potassium level, it seemed to me, was low
14 in this patient - only about 2. So, it is conceivable
15 that despite a low concentration of digitalis, we
16 might have been seeing an exaggerated effect due to
17 the low potassium, as one analyzes it completely.
18 But, overall, while we do raise concerns on the last
19 page of this review, we concluded on balance that
this patient did not have digitalis intoxication
because of those factors.

20 Now, I think it is fair to hold to
21 that analysis here. Had we had other changes in
22 rhythm that I could have isolated from the basic
23 disease, we might have come up with a stronger

24

25



1

2 inclination to list this as digitalis intoxication.

3

Q. I just have one other question
arising from that.

5

If you have a child who has low
potassium --

6

A. Yes.

7

Q. -- and because of the low
potassium is predisposed to an exaggerated response
to digoxin but has a very low digoxin level, serum
digoxin level, if that child exhibited signs of what
would otherwise be digoxin intoxication, would you
still consider the child to be under the effects
of digoxin intoxication, notwithstanding a very low
level?

14

A. I think one would definitely be
pushed into that direction, yes.

15

I think the answer to your question
is, yes.

18

Q. Thank you, doctor.

19

Could you turn to Barbara Gionas,
which is a Hospital record you should also have
right beside you.

21

A. I have that.

22

Q. Doctor, my questions again arise
out of things that I see in the chart that you did not

24

25



1

2 make reference to, and I would like you to turn to
3 page 73 and your Chart Code No. 36.

4 In part III B, you point out under
5 March 3 to 7: "emesis x2 - (dig. intox.?)"

6 That is in your note?

7 A. Yes, that is right.

8 Q. On pages 73 and 74, there is
9 a note by Dr. Kobayashi where he reviews a number
10 of things and then writes: "Impression - digoxin
toxicity".

11 A. Yes.

12 Q. Based upon what he has
13 transcribed, did you not agree with his diagnosis?

14 A. Yes, obviously, I did since
15 we -- my notes here, by the way, are -- the fact that
16 I put digitalis intoxication into this document
17 really is not to imply that that was my conclusion at
that time.

18 Does that follow?

19 Q. Yes. The question mark there.

20 A. Digitalis intoxication
21 really was taken from the chart, and this is my
22 notation as to what was reported in the chart.

23 So, the fact that digitalis intoxica-
24 tion is written down there does not mean it was my

25



1

2 interpretation at the time.

3 Q. So, this is what you took
4 out of the chart?

5 A. Out of the chart, and I think,
6 under the circumstances, I would not have found too
7 much to argue with. I would have agreed with what
the physician here infers.

8 Q. When you rated these
9 children on a scale regarding exhibiting signs of
10 digitalis intoxication during their stay in hospital,
11 this child scored a zero.

12 A. I see this.

13 Q. My question is: Why?

14 A. I think that is a good
15 question. One of the reasons I think that we felt
16 this was that the only evidence that we had that
17 this patient was having any digitalis intoxication
18 was the fact that the patient had emesis. That was
19 really the only sign. We had no electrocardiographic
tracings to show arrhythmia.

20 One of the strongest pieces of
21 evidence that we tried to use here - not one of the
22 strongest but a strong piece of evidence on this -
23 were the electrocardiographic tracings taken,
particularly if they were obtained at a time when

24

25



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2 other symptoms were present. If there is electro-
3 cardiographic evidence to suggest that these patients
4 were having arrhythmias at that time, I think that
5 would be very helpful because I am looking through
6 here and I do not see any evidence that we have on
the EKGs that showed an arrhythmia.

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DM.jc
BB

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2 Q. Well, at pages 379-383.

3

A. Okay.

4

Q. There are notes, just notes
from Dr. Contreras.

5

Q. Let's say:

6

"ST changes ? digoxin."

7

A. Well, I have those in my review
also.

9

Q. Dr. Moller has them down under
rhythm strip in Exhibit 314.

11

A. Right. Now that of course we
interpreted as so-called digitalis effects. You know,
I have been trying to analyze this to indicate that
the digitalis effect is not synonymous with digitalis
intoxication. We did not see any arrhythmias and I
have been thinking it over now, and I have the sense
that the group collectively felt that this was not
a patient that had sufficiently strong evidence for
toxicity, at least hard data. I imagine now perhaps,
in the course of this testimony, that we might have
upgraded that a little bit, but I still think it is
not in the category at least of those patients that
we have seen in the 7 and above range.

22

Q. But it might have got into the
medium category?

24

25



BB.2

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2 A. Perhaps.

3 Q. Suspicious type?

4 A. Perhaps one might have put it
5 in that category. I think another issue that we were
6 using, and again with the same caveats we have
7 brought up, the blood levels on these patients were
8 considered to be in a relatively normal range, we had
9 6 or 7 measurements, with the exception of the post
10 mortem I guess that was a little elevated, was it not?

11 Q. These were tissue levels.

12 A. Oh, we have no serum post mortem,
13 I am sorry.

14 Q. No?

15 A. But the serum levels that were
16 taken ante mortem, at least clearly on in this patient's
17 course, well even the ones taken up on 3.7, appeared
18 to be quite low, 1.2. So we put this all together
19 in the absence of the arrhythmias, the low blood level.
20 The only thing we had was that episode of emesis, and
21 I note here that there was some slowing of the heart
22 rate and perhaps one might have given that a little
23 higher number in our scoring system.

24 Q. Now, notwithstanding the article
25 that we previously discussed where there may not be
this correlation between arrhythmias and levels.



BB3

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A. Yes.

2

Q. You still, when you discussed it,
you still rated this a zero and that was my concern.

3

A. When we discussed it with the
team you mean?

4

Q. Yes.

5

A. Yes, that was the consensus.

6

Q. Well, where would you personally
rate this now in the scale of 1 to 10?

7

A. I might put a little more
emphasis on this and bring it up into the, oh, 3 or 4
possibility.

8

Q. Doctor, could you look at your
code number, I think it is 13.

9

A. Yes.

10

Q. Matthew Lutes.

11

A. Pardon me?

12

MR. LABOW: Page 77, Mr. Commissioner.

13

THE WITNESS: Who is that?

14

MR. LABOW: Q. I think it is No. 13,
Lutes, Matthew Lutes.

15

A. Go ahead.

16

Q. Now, I can tell you that Dr. Rowe
told us in evidence in Volume 14, page 2437, that the
digoxin in this case was held because it was held at

17

18



BB. 4

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2 one point, because although the level was only about
3 2.1 it might have been too high for this child. I
4 would like you to turn to Dr. Moller's note,
5 Exhibit 314 on this child, and I know you have some
6 difficulty interpreting what this means. I would
7 like to see if you can help me somewhat.

8

A. Go ahead.

9

Q. Now, at the very top --

10

THE COMMISSIONER: I am sorry, I just
have to find it yet.

11

MR. LABOW: It should be page 9 of that.

12

THE COMMISSIONER: I have a beautiful
index but then the pages are not numbered.

13

MR. LABOW: Q. Dr. Moller seemed to write:
"Q brady and dig. level."

14

The Q means question?

15

A. Yes. I think that is what I
told you, or suggested that meant, bradycardia
probably, but we can find out easily enough.

16

THE COMMISSIONER: I am sorry, you say
he said Question?

17

THE WITNESS: The "Q" on top of the page.

18

THE COMMISSIONER: Oh, I see that is
Question, yes.

19

THE WITNESS: I am going to submit this

20

21

22

23

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BB.5

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2 to you next week and re-clarify that, but go ahead
3 and assume that is what it is.

4 MR. LABOW: Q. At the very bottom of
5 the page --

6 THE COMMISSIONER: When you say --

7 MR. LAMEK: What Dr. Mirkin means he
8 suggested that he have the Moller material retyped
9 and corrected just for the spelling and so on and send
it to us in a more readily comprehensible form.

10 THE COMMISSIONER: Yes, all right, thank
11 you.

12 MR. LABOW: Q. Now the very bottom line
13 above 1 EKG: "Held dig. although 2.2 toxic".

14 A. Yes.

15 Q. This would seem to me to be the
16 same view as Dr. Rowe had, that 2.2 was probably too
high for this child?

17 A. Well, I think that you have to
18 understand that this statement is probably an obser-
19 vation that was made in the chart, that that is not
20 Dr. Moller's conclusion from the observations made,
21 okay. I am sure that somehow if we look through the
22 zebra chart of this patient we will find this wording
23 in there, that probably reflects that, whoever made
24 that observation, Dr. Rowe or an associate, that would

25



BB.6

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2 be my interpretation of that comment.

3 You see if Dr. Moller had felt we had
4 a strong case here for intoxication he would have
5 voted that and it would have showed up in these scores.
6 I think this particular patient had a low score also.

7

Q. 2.2.

8

9

10

11

A. Well, since it was a very narrow range of variation, you know, of these I think that really reflects our collective thinking on the subject, at least to the best of our ability to interpret the data.

12

13

14

Q. Do you recall whether Dr. Moller was strongly, or not strongly one way or the other indicating what he thought the data meant?

15

16

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19

20

A. Well I think it is a little difficult for me to recall that particular point. I certainly will be able to get his information for you if you like and it will be helpful to the Commission, it will be very easy for me to get and I will be delighted to do it. So I give you as accurate a portrayal of his interpretation of this as is possible.

21

Q. Okay.

22

A. I will do that then.

23

24

25

Q. Thank you. Now, my only other question concerning Real Gosselin, and this is page 49



BB. 7

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2 of Exhibit 313, and it is your Code No. 29. Now,
3 once more in No. 8, the final note with the asterisk
4 says:

5 "Suddenness of change in clinical
6 condition supports intoxication
7 particularly in absence of any
8 significant alteration ... ",

is that correct?

A. That is correct.

Q. " ... in pathophysiological
11 process."

What kind of alteration were you
thinking about that may have changed your opinion?

A. I guess one thing here that
14 always caused some problem for me and it did through-
15 out this evaluation was isolating events that could
16 have been going on concurrently with the high or even
17 low digoxin concentration in these particular patients.
I was essentially, if you will note on the first
18 page of this individual under Item III B, significant
19 events at 12.17 p.m. you will see "respiratory
20 arrest, electrolytes normal."

One of the things that we were trying
22 to correlate were some of these plasma concentrations
23 with the electrolyte status of the individual.

24

25



BB. 8

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2 Particularly in a patient like this where we had
3 concentrations of - this one I think we had 3.9, we
4 were, I was interested in the evaluation at least
5 in attempting to determine whether this patient had
6 low potassium which might have accentuated the effect
7 of that particular concentration.

8 We also had a patient here who had seemed
9 to be manifesting a good response to some treatment
10 up to the time of death, although I see that this
11 patient was not responsive to the prostaglandin, but
12 had been responsive to the Lasix given to the subject.
13 So by that I meant there had been no general change
14 in the status of this particular patient.

15 Another possibility that I was concerned
16 about was the well known effect of oxygen deprivation
17 on digitalis intoxication. Now the fact this patient
18 had apnea the day before in its hypoxic state this
19 may have enhanced the state of the digoxin as well.
20 So those would have been the general types of changes,
21 the pathophysiologic changes we look for.

22 Q. What is the effect of oxygen
23 deprivation on digitalis intoxication?

24 A. Well, I think probably most
25 people would feel that tissue that is deprived of
 oxygen probably shows increasing sensitivity to these
 drugs.



BB. 9

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MR. LABOW: Thank you very much, I
have no further questions, Mr. Commissioner.

THE COMMISSIONER: Thank you.



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2 THE COMMISSIONER: Thank you.

3 Mr. Shanahan.

4 CROSS-EXAMINATION BY MR. SHANAHAN:

5 Q. Good afternoon, Doctor, my
6 name is Shanahan and I act for the parents of two
7 of the children, the Lombardo and Dawson children.
8 Now, mind you, after hearing the evidence that you have
9 given with respect to Lombardo and the explanations
10 you have given of your numbering system I really don't
have any questions on the Lombardo child.

11 But I am a little concerned about
12 your arrival at a rating for Baby Dawson from an
13 observation of her clinical symptoms in arriving
at a rating, I believe it was zero.

14 Now, looking at that exhibit first
15 of all here, Exhibit 313, on the conclusion I am
16 looking at, as it is numbered here, page 24. Do
17 you have that, Doctor? One of the things that struck
18 me first of all where it says in the last paragraph
here:

19 "Digitalis intoxications: Present,
20 Absent."

21 First of all, it doesn't seem to be a wholehearted
22 conclusion here by saying probably absent. Then
23 in reading the last comments here, in line 4 it

24

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M/PS



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2 acknowledges that the cause of death is unclear.

3 Do you have that located, Doctor?

4 A. Yes.

5 Q. And then there is a part
6 stroked out and concludes: "No clear evidence of
7 digoxin intoxication."

8 It struck me, Doctor O'Dea I think
9 is the individual who was looking at this particular
10 set of charts and it struck me just right there that
11 there certainly didn't appear to be, in his mind,
12 a categorical rejection of the possibility of
13 digitalis intoxication. He says here there is no
14 clear evidence. Does that suggest to you or did it
15 suggest in your discussions that maybe there was some
16 indication clinically that this child may have suf-
17 fered from digoxin intoxication?

18 A. Well, we didn't reach that
19 conclusion, as you see. The information that we had
20 on this particular patient consisted of again a
21 plasma level that was consistent with the normal
22 therapeutic range. We had very little evidence of
23 any arrhythmias, we had no evidence of even some
24 softer signs of digitalis intoxication and I think
25 that was the basis for the judgment. I guess had we
had more information it might have been possible to



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2 come up with a clearer -- it is not an ambiguous
3 statement. To say "probably", I guess I probably
4 would have eliminated probably and said absent.

5 Q. All right. I am not going
6 to belabor the issue here, but if I could just show
7 you or take you through just a few pages here of
8 Dawson's medical chart, the chart that presumably Dr.
9 O'Dea would have looked at, Exhibit 69, because they
10 troubled me and if I could ask you to direct your
attention to them when you have them.

11 A. Sure.

12 Q. In that volume you have, sir,
13 if you could turn to page 85. Now, when I was reading
14 the last few days I bear in mind, sir, that this child
died on July, I believe it was 27th or early 28th, and
15 the last reading I believe that you had, a serum
reading was 1.9 on the 24th, that would be three
16 days earlier.

17 Now, that indeed perhaps and the
18 levels we have been given wouldn't cause great
19 concern but then the days following, as I looked at
20 the nurse's notes, it struck me that some of the
21 symptoms of others in your profession have said
22 would be symptoms of digoxin overdose seem to me
23 to be coming into the records of Amber Dawson.

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Now, page 85 of those records, if you could turn to it, that is the note there on the top of page 85 of July 25th and under Behavior there it says:

"Appeared drowsy, slept continuously between feeds."

And then at the bottom again in nurse's handwriting on July 26th under Behavior it says:

"Very lethargic all evening -- limbs appear almost floppy at times."

And then turning back to page 80, although we are turning back we are really going forward in time. On page 80 of those records, July 27th prepared by Nurse Nelles it says under Behavior, around the middle of the page, Doctor "Continues to be lethargic". Under Nutrition "Dr." Reynolds notified re. babe's poor nutritional status and lethargy."

The terminal notes written up by Dr. Reynolds, I think they are Reynolds, at least on page 84, they speak there, sir, the heavy dark writing there, line 3 of that heavy dark writing speaks of a sudden recent deterioration and collapse and coming down a few lines extreme bradycardia in spite of heroic efforts there, there is just no return, the last three lines here, of any electrical activity at all.



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Now, as I look at that, sir, it would suggest to me possibly, bearing in mind that vomiting is maybe a nonspecific symptom, but still, that in fact you may well have there a symptom of, in the last few days without a serum reading, you may well have a symptom of digoxin intoxication.

A. I would have a lot of trouble buying that one.

Q. All right.

A. The main point I think you are raising, and correct me if I have missed it, within the behavioral observations the patient being drowsy, the suggestion that there is some loss of muscle tone, the floppiness.

Q. Yes.

A. We don't see too much here on emesis occurring, I didn't see any, as a matter of fact. You know, the slowing of the heart rate and the terminal event, you know, a lot of this could have just come about from impairment of the respiratory system and I think we had the patient that was showing some respiratory distress. Now, whether one wants to attribute this to drug intoxication one could make that proposal but I have difficulty because we don't seem to see any reported irregularities in the



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2 rhythm.

3 If you will notice on page 80,
4 July 27th, now, this is right before the arrest, the
5 patient's apex is being described as 130 to 106 and
6 regular. Admittedly, you know, I think a cardiologist
7 might argue, and correctly so, that the apex beat is
8 not a good way to discern irregularities. Now, ob-
9 viously if we had electrocardiographic tracings
10 at that time, and I must confess I don't know where
they are.

11 Q. No.

12 A. Or if they were taken. I
13 shouldn't infer that they were taken and not made
14 available but that might have helped us and I think
helped you.

15 Q. But in terms of giving you
16 an overall picture, bearing in mind that this child
17 here, and it is noted in your other records there,
18 her age, eleven months, that she had already had
19 successful surgery, a banding, that she had returned
20 to the hospital not because of any precipitating
21 event, it was just nutritionally she was poor, her
22 weight was down, she was back in to have her overall
23 condition reassessed. On the horizon there was talk
of surgery to assist her with respect to the phrenic

24

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2 nerve paralysis, but certainly nothing urgent was
3 scheduled. But within five days there would be this,
4 especially in the last three days after that last
5 reading, there would be this real deterioration sud-
6 den enough and unexpected enough that somebody would,
7 as you can see from the records, notify the coroner
and have an autopsy done.

8

Now, surely that would be part of
9 the clinical picture that you would sort of be aware
10 of and appreciate as you would sort of sum up whether
11 in fact there was something dubious about the symptoms
she was exhibiting.

12

A. Well, we couldn't really
13 discern I think whether this patient might have fit
14 into the unexpected category, which is something you
15 are implying.

16

Q. Yes.

17

A. And, you know, it is important
18 to recognize that this patient did have pneumonia on
January 23rd.

19

Q. On what date, I'm sorry?

20

A. This patient on January--
I'm sorry, July 23rd, 1980. The notation is made,
21 bilateral patchy consolidation of the lungs. In
22 layman terms that is pneumonia.

23

24

25



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2 Q. Yes.

3 A. And that is an X-ray

4 description which would suggest that some fluid or
5 infectious process was in the lungs. That doesn't
6 surprise me. You see, you have a patient here in whom
7 the large blood vessel bringing blood to the lungs
8 has been banded. This patient also in 1980, that
band was taken off in May.

9 Q. That's right.

10 A. The patient may have been,
11 you know, the patient is described as a cyanotic
12 malnourished little baby. Now, that is not a healthy
13 child. Now, nor would I want to imply from that
14 statement that one would expect a death in four days
after admission.

15 Q. She has lived at home after
16 all with her mother and received a dosage and
17 been cared for by mother. So, I am sure you will
18 bear that in mind.

19 A. Oh, surely. Now, I think
20 that is an important point and I don't want to infer
21 that this is a sick child, but not necessarily one
22 that is going to die right away in four or five days
in the hospital.

23 Q. All right.

24

25



1

2 A. Okay.

3

Q. Now, would you have had -- I'm
4 sorry, have you finished, maybe you haven't.

5

A. No, that's all right.

6

Q. All right Would you have
7 had the autopsy report available? Perhaps that is
something that someone else has asked you.

8

A. I think we did.

9

Q. All right.

10

A. No, I am sure we did, we had
11 all the charts, I had this chart and we went through
it, or my colleague did and we have here in the autopsy
12 report gastric perforation, hemoperitoneum, you had
13 blood in the peritoneum cavity, you had some de-
14 generation of the central nervous system and there
15 was closure of the septal defects. But you had a
16 patient who was in a very poor nutritional state. I
17 don't think we should infer it is a healthy child and
18 I don't want to overdo that, but the question comes
19 up would these findings have been attributable to the
patient's primary disease. I would submit to you that
20 the pneumonia is consistent with this patient's
21 disease.

22

Q. All right. Can I just show
23 you then to get into the autopsy report briefly here

24

25



1

and then that will conclude my examination here.

2

It is in that large volume you have there.

3

A. Can you give me the number,
please?

5

Q. It commences on page 59.

6

The area first of all, page 63 about the microscopic
and laboratory findings here from the laboratory. The
lungs, it says:

9

"The sections show areas of collapse
and overdistension. There is also
congestion of pulmonary vessels.

11

No evidence of recent or old pneu-
monitis is seen."

13

Now, does that fly in the face of
what you just said about pneumonia?

15

A. No. I would take the lab
data and it would suggest that the X-ray, the
interpretation of the X-ray would have been suspect.
You know, that is odd. Is this the microscopic
findings?

19

Q. That's right. It would seem
to me as a layman that it is saying that it wasn't
pneumonia.

22

A. I think it would say to me
as a physician that there is no pneumonia there, I

24

25



1

2 accept that.

3

4 Q. All right. Let's put that
5 aside for a moment. Page 61, it does confirm here
6 about the recent perforation of the stomach. Dr.
7 Rowe felt that in trying to get to the bottom of why
8 this child and how it died, the cause of death,
9 he felt that maybe as sick as she was and as weak
10 as she was and what have you that this perforation
could have perhaps triggered that final deteriora-
tion.

11

A. Yes.

12

13 Q. Now, I point out to you here
14 that if the vomiting that I have suggested to you,
15 the persistent vomiting over that last three or four
16 days in fact has caused this perforation, has been
17 so violent and so persistent as to cause that
18 perforation, again, I return to the proposition could
that be vomiting of a nature that was induced or
caused by perhaps digoxin toxicity?

19

A. I didn't say the vomiting -

20

I didn't ---

21

Q. This was what I pointed out
22 to you earlier that we had looked at and you felt
you didn't read as much into it as I did.

23

A. I didn't see it, what page

24

25



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2

was that on?

3

Q. Page 80, page 85.

4

A. Yes.

5

6

Q. The floppiness, the lethargy

and prior to that the vomiting.

7

A. Could you show me where the
emesis is described, do you mind?

8

Q. I will try.

9

A. What page is it?

10

Q. There is one reference here
on page 79.

11

A. Okay, on page 79, I see it.

12

Q. 79, but that says just once.

13

A. Yes.

14

Q. When the nurse forced some
milk and I don't know if forcing milk in itself may
well have --

15

A. No.

16

Q. Page 86 here, again, the
reference around 10 lines from the top there where
the writing style changes, a reference to the lethargy
during the course of the day, "Not interested in
feeds and vomited twice."

21

A. Yes, okay.

22

23

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12jan84 2

Q. Indeed, I had others, sir.

DD

DPrc

3

I regret that I did not show you more.

4

A. That is fine. That is okay.

5

Q. Again, as a layman here, I am tying persistent vomiting with perhaps perforation in the stomach lining because there does not seem to be any other reason why her stomach lining would be perforated.

9

A. Do you think the inference

is that the emesis caused the perforation?

10

Q. I am asking, could that have happened?

11

A. I don't find that terribly likely.

12

Q. You don't find it likely?

13

A. No. I think perhaps other factors might. Stress ulcer, in this patient, would be, to me, a more likely possibility.

14

Q. Stress ulcer?

15

A. Yes.

16

THE COMMISSIONER: Is that shown in the autopsy?

17

THE WITNESS: I think they just

18

describe -- they show an area of recent perforation, hemorrhage and some adhesions.

19

THE COMMISSIONER: Would not the

20

21



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DD2 2 ulcer be apparent on the autopsy?

3 THE WITNESS: It depends. I think
4 it would have been. They just show the perforation.

5 The point I am making is that I
6 think it is well known that infants who are in
7 stress can develop ulcers - ulceration - and whether
8 that was also the basis for the perforation, I raise
that possibility.

9 I am not aware, I should put it,
10 that persistent vomiting induced by this would be
11 a likely cause of perforation.

12 THE COMMISSIONER: What about this
13 then? Looking at page 63, under Item 7:

14 "Gastromalacia with perforation of
15 the cardia was a recent event most
16 likely precipitated by vomiting."

17 What does that mean?

18 THE WITNESS: That is what this
gentleman is inferring.

19 THE COMMISSIONER: Yes. Do you
think -- I always thought that an ulcer, if it
20 existed, would have been apparent on autopsy and
21 would have been included.

22 THE WITNESS: I think the ulcer
23 crater would have been apparent on autopsy but, if
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2 DD3 the perforation occurred at the site of the ulcer-
3 ation, it might have been obliterated.

4 Again, this is very speculative,
5 what I am doing, and I am unable, I think, to provide
6 a further stronger relationship between the symptoms
7 you are describing and the likelihood of digitalis
intoxication in this particular patient.

8 MR. LABOW: All right.

9 Q. One final thing --

10 THE COMMISSIONER: If I could just
11 interrupt for a moment.

12 The perforation itself, how serious
13 is that? Can that cause death in itself, perforation
of the stomach?

14 THE WITNESS: Oh, yes, put the
15 patient into shock.

16 THE COMMISSIONER: Have you any
17 opinion on this one, whether the perforation was a
18 major cause of death?

19 THE WITNESS: I don't have any data.
20 It is not in the chart, at least in the summary of
the chart, but if the patient, on the day preceding
21 death, or the 26th of July, was showing signs of
22 shock, I think that would have been consistent with
23 the perforation having occurred at that time.

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DD4 2 On the 26th of July, this patient
3 was showing reduced heart rate and respiratory
4 distress, possibly symptoms that could be associated
5 with a shock-like state, which could be induced by
6 a perforated ulcer definitely.

7 I think that is not impossible or
8 maybe even --

9 THE COMMISSIONER: If you said
10 a perforated ulcer, I understand that, but a perforated
11 ulcer does not necessarily produce a perforated
12 stomach. If the ulcer is in the stomach and per-
13 forates, it could cause all sorts of damage to the
14 stomach but it does not necessarily perforate the
15 stomach, does it?

16 THE WITNESS: No, it does not. But
17 if it does -- if the lining --

18 THE COMMISSIONER: The thing that
19 concerns me is that the autopsy seems to say that
20 the perforation was most likely precipitated by
21 vomiting, and you are suggesting that the perforation
22 was most likely precipitated by a perforated ulcer.

23 THE WITNESS: The word "gastromalacia",
24 it refers to the thinning of the gastric wall. What
25 is the cause of that? Usually, when we talk about
ulceration, we are thinning the wall or decreasing the



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DD5 2 width of the wall so that it becomes more vulnerable
3 to bursting, to frank perforation.

4 When you have frank perforation, you
5 have bleeding and you could have the sequela that
6 was observed here. But I think that I can't confirm,
7 based on this pathological report, that that
8 occurred.

9 On the other hand, the blocks from
10 the Pathology Department will have all these tissues;
11 they don't throw those out. If you think it is worth
12 looking it, you can have them cut some more sections
13 and take another look at it.

14 MR. LABOW: Q. One final area here
15 is that, in that paragraph 7 where it does summarize
16 the abnormal findings, you see where it says:

17 "The autopsy showed the surgical
18 repair of congenital heart defects
19 has been successful. Ventricular
20 and septal heart defects have been
21 closed and appear intact."

22 Under paragraph 8, where there was
23 a place to comment on the cause of death:

24 "The immediate anatomical cause of
25 death not determined."

Specifically commenting on the



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2 DD6 operations on the following page - and I won't read
3 all of it, but where it specifically breaks down
4 under paragraph 9, the heart, under "final impression",
5 under sentence No. 1 and No. 3, it indicates that
6 the techniques and the surgery that were used to
7 close the septal defects were all completed and the
8 comment on both of them, I think, says, "with
excellent surgical result."

9 To me, as a layman again, it would
10 appear that Amber Dawson had gone in, had been
11 properly assessed, had been properly treated, the
12 techniques had been done properly. This has been
13 confirmed in an autopsy that you would be able to
14 look at. It was confirmed in autopsy as well that
15 there was no pneumonia and confirmed in autopsy that
16 there had been perforation of the stomach lining,
which was recent and precipitated by vomiting.

17 Again, I guess I am just harping
18 at the same thing, would that not then be suggestive,
19 and this pathologist not being able to come to a cause
of death, suggestive of perhaps digoxin intoxication?

20 A. I think the most we could
21 go here -- I don't think that would be suggestive of
22 digoxin intoxication at all, in my mind. I would,
23 I think, agree with you that, on review here and as

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DD7 2 we indicated in this document, the cause of death
3 is unclear.

4 Q. Yes.

5 A. I think maybe that category --
6 this patient could be included in our uncertain cause
7 of death group, perhaps, and probably, I think, would.
8 But I really cannot put this together in sufficient
9 clarity or commitment to say with any degree of
assurance that this was digitalis intoxication.

10 In light of that, I would rather
11 not. I think that is the fairest way to assess it.

12 Q. You would rather leave it
13 that her cause of death is just uncertain and put
her in that uncertain category?

14 A. I think that is about all I
15 can do.

16 MR. SHANAHAN: Thank you, doctor.

17 THE WITNESS: Thank you.

18 THE COMMISSIONER: Thank you, Mr.
19 Shanahan.

20 Mr. Lamek, what would you like?
21 Would you like a break?

22 MR. LAMEK: Perhaps just a short
break, if we could, Mr. Commissioner.

23 THE COMMISSIONER: It can be as long
24
25



1 DD8 2 as you like. We don't have to take a short one.

3 People may want coffee. If we take fifteen minutes,
4 is there any remote possibility that we will not
5 finish?

6 MR. LAMEK: Not the slightest.

7 THE COMMISSIONER: Let us take
8 fifteen minutes then.

9 --- recess.

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1 --- on resuming.

2 THE COMMISSIONER: Yes, Mr. Lamek.

3 REDIRECT EXAMINATION BY MR. LAMEK:

4 Q. Dr. Mirkin, while we are
5 dealing with the question of Dawson, the child that
6 you were last discussing with Mr. Shanahan, do you
7 still have the chart available to you, please?

8 A. Yes, I do.

9 Q. I would like to ask you just
10 a couple of more questions about the stomach perfora-
11 tion. Could you turn to page 63, please, in the
12 autopsy report. You have postulated the possibility
13 of an ulcer which may have been at the site of the
14 rupture that was found at autopsy. At the top of
15 page 63 we see there are microscopic and laboratory
16 findings briefly summarized. The third item relates
17 to "stomach" and reports:

18 "Sections through the area of
19 perforation shows hyalinization
20 and thinning of muscular coat. In
21 areas adjacent to the rupture, the
22 blood vessels are distended and there
23 is interstitial hemorrhage."

24 Are those reported findings of any
25 significance with respect to your postulation of
 the possibility of an ulcer?



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2 A. The hyalinization and
3 thinning of muscular coat suggests that there may have
4 been some long standing effect on that region of the
5 stomach that ante-dates that perforation.

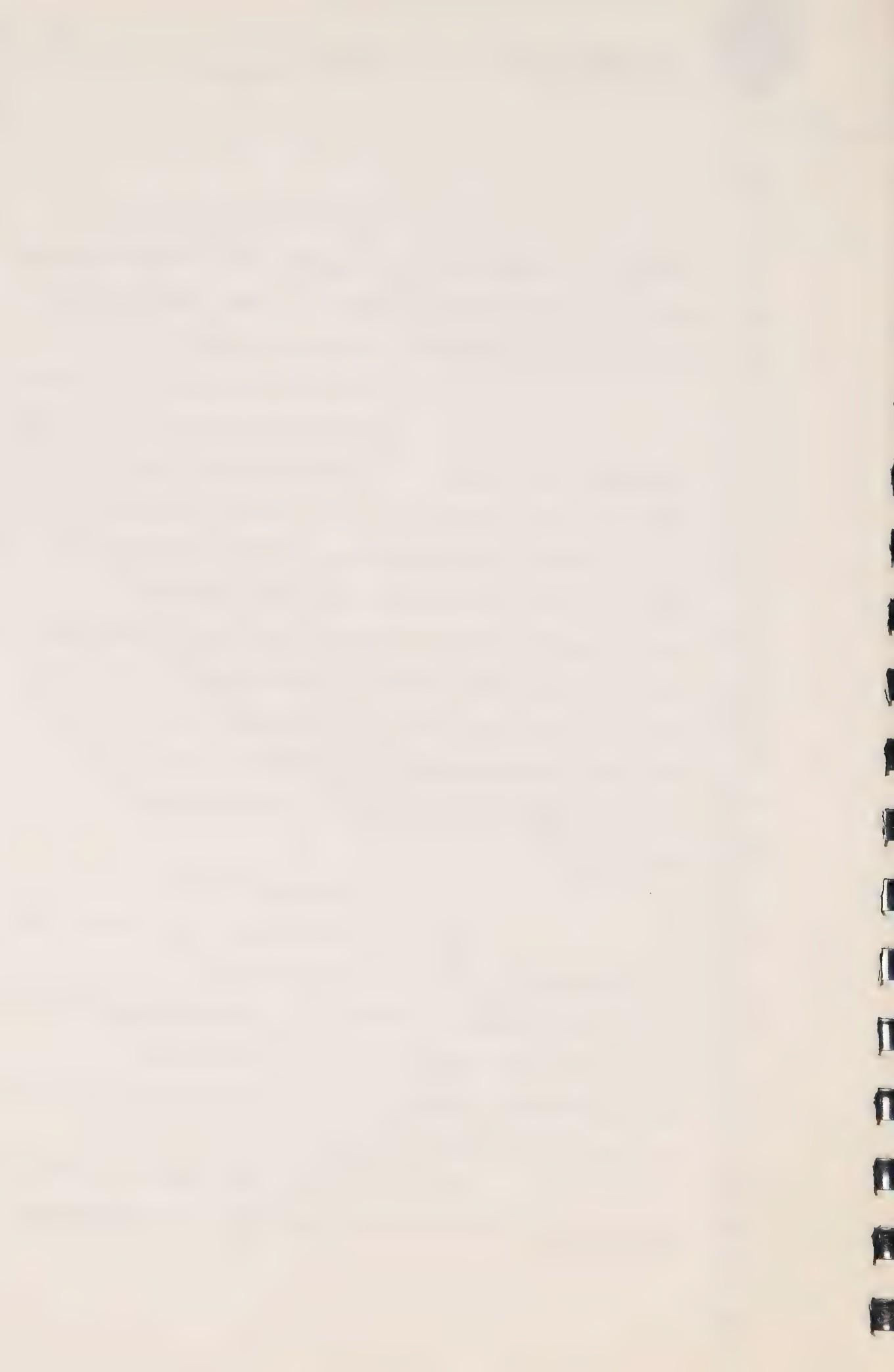
6 Q. What is hyalinization, please?

7 A. I am trying to give the most
8 accurate definition. I believe we refer here to the
9 change in the structure of the normal lining of the
10 stomach to one that consists of connective tissue,
11 fibrous tissue instead of the normal mucocele
12 cells that lie in the stomach, and the hyalinization
13 to me would infer change in the composition of these
14 cells so that they had a consistency that was rather
15 uniform. Hyalinization, the term hyalinization I
believe refers to the staining characteristics of the
cell.

16 Q. The staining characteristics?

17 A. The staining characteristics
18 of the cell, of the connective tissue. It is
19 clear as I stumble around for a good description that
20 I am unable to give one that is going to be
21 pathologically precise. I perhaps should not attempt
22 to and look it up before I do that.

23 Q. Doctor, do those reported
24 findings as you understand them lend any support to





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2 or are they consistent with your hypothesis of ulcer?

3 A. Well, I think that it might
4 go along with it. If one suggested that an area
5 of the stomach was indeed undergoing change prior to
6 these periods of emesis.

7 Q. Yes.

8 A. Then I would postulate that
9 this particular location might have undergone sufficient
thinning to perforate.

10 One of the points to be raised here
11 is whether or not blood had been shown on the gastric
12 aspirate of this patient. Obviously if a patient
13 is having a gastric ulcer of any consequence they may
14 pass some blood in the stool, or it might be found
15 in the aspirate from the patient's stomach.

16 I don't know if any record of that
17 exists in the chart, and one could use the absence
18 of that information as a negative vote against that
hypothesis.

19 Q. In the light of that, perhaps
20 more significantly in light of the fact that there does
21 not appear to be any clear evidence as I understand
22 you in support of the hypothesis of perforated
23 ulcer, is there any other explanation, other than
24 the one which Mr. Shanahan suggested to you, as to
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2 the way in which this perforation of the stomach
3 may have occurred, that is other than as a result of
4 the emesis; the heaving, I take it this child
5 experienced.

6 A. Well, certainly perforated
7 ulcers or stomachs occur as a consequence of having
8 a tube down. One could visualize a tube being passed
9 and the perforation does occur by that route. I
10 don't know if this child had a forceful feeding
11 tube or anything of that sort described in the
record.

12 Q. In any event it is clear,
13 is it not, from the same page 63 that Dr. Cutz, the
14 pathologist at the hospital who performed this
15 autopsy for the coroner, he does not appear to have
16 considered the stomach perforation as a contributing
element in the death of the child.

17 A. That is what one would
conclude.

18 Q. Therefore perforation of the
19 stomach notwithstanding the cause of Amber Dawson's
20 death still remains something of a mystery.

21 A. Yes, I think it does.

22 Q. If I may, Dr. Mirkin,
23 briefly, just a very few questions arising out of

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2 matters covered in one or the other of the cross-
3 examinations.

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5 Mr. Brown yesterday referred you
6 to the results of what we call the gutter blood
7 study in the context of a discussion of Janice
8 Estrella and that child's death. In particular, he
9 showed you the particular results of that study, and
10 I think you will agree with me that although you
11 have not seen the particular results, the substance
12 of the results had been outlined to you prior to
13 your giving evidence.

14

15 As I understood you, you said that
16 the reasonably good correlation between all but one
17 of the results reported in gutter samples and levels
18 reported in heart blood from the same children
19 enabled you to have a reasonably good confidence
20 level in the 72 nanogram level reported in Estrella,
21 notwithstanding that there was one extremely high
22 and anomalous gutter level in the study. That is a
23 rather tortuous way of summarizing your evidence,
24 but do I put it fairly?

25

A. Perfectly accurate.

26

27 Q. In short, the existence of
28 the one anomalously high reading of the gutter
29 blood study does not greatly shake the confidence

30

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2 that you are prepared to place in the post mortem
3 Estrella sample.

4 A. Correct.

5 Q. And as I therefore understood
6 it you are prepared to revise again, or re-revise
7 your opinion as to the probable involvement of
digoxin in the death of Janice Estrella.

8 A. Based on this post mortem
9 information.

10 Q. And do I understand that you
11 are now inclined to think that digoxin intoxication
12 did indeed play a part, if it was not indeed the cause
of Janice Estrella's death?

13 A. I think that is correct.

14 Q. Now, Doctor, I am obliged
15 to tell you that others who have preceded you in the
16 witness box here, that is to say in particular Doctors
17 Kauffman and Hastreiter, have said, having reviewed
18 the same data from the gutter blood study, that although
19 they would not completely discard the Estrella sample,
20 their level of confidence in that sample has to be
21 reduced very considerably, and indeed Dr. Kauffman
22 as I recall it reduced the child from a 5 to a
23 2 or something of that sort, and 5 was the top of
his range and 2 was barely suspicious, and Hastreiter

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2 made a similar adjustment in his assessment of the
3 likelihood of digoxin involvement.

4 I am interested of course in the
5 very different attitudes which you have taken to the
6 gutter blood study numbers. Can you tell me how it
7 is you feel able to virtually discard the enormously
8 high number in the gutter blood study and maintain
your confidence in the Estrella number?

9 A. The decision I made in that
10 regard is based on the following reasoning. We had,
11 as I recall, 13 patients analyzed.

12 MR. YOUNG: Fourteen.

13 THE WITNESS: Fourteen patients
14 analyzed in whom heart blood was obtained, cardiac
15 puncture blood and blood levels determined. We had
16 14 so-called gutter 1 determinations, and the
17 relationship between 13 of the 14, that is the ratio
18 of gutter 1 to cardiac blood was in a relatively
19 constant relationship with the exception of that
20 one analysis. We had further gutter 2 blood
21 obtained in which the relationship between the gutter
22 2 blood and the gutter 1 blood was, the correlation
23 was very high, in addition to which by virtue of that
24 fact, with the exception of that one sample, the
correlation between gutter 2 blood and cardiac blood
was also quite constant.

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That means, as I analyze the data,

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27 out of 28 determinations were on line.

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Q. I don't think there were quite
28.

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THE COMMISSIONER: No, I think it was
26 out of 28.

6

THE WITNESS: 26.

7

THE COMMISSIONER: No, 25 out of the 28
because two of them ---

8

9

THE COMMISSIONER: Perhaps we should
look at the actual results.

10

11

THE WITNESS: Okay.

12

MR. LAMEK: Q. So that we are not
having to rely on memory. I think it was 238.

13

14

THE COMMISSIONER: I think two of them,
that's my recollection, that two of them they didn't
test in Gutter 2.

15

16

THE WITNESS: Okay. Well, I don't
think that I will modify my answer.

17

18

THE COMMISSIONER: It doesn't make
any difference.

19

20

THE WITNESS: Not to me.

21

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THE COMMISSIONER: No, I am getting -
I guess it is only Thursday afternoon and I am
getting picky about these things, but you are quite
right.

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MR. LAMEK: We are talking about Exhibit 238, Dr. Mirkin. Just so that we are absolutely confident in the numbers about which you're talking about.

THE WITNESS: That is correct.

MR. LAMEK: Q. Yes.

A. Now, there are two pieces of information. Do you all have copies of this, you are all familiar with it, I presume? If one were to do a statistical analysis of these data it is clear in my mind without even doing it right here publicly that we would come up with a highly significant relationship, I would say in the order of probability of 1, less than one in a thousand that $P = .001$ maybe would even be $P = 0.001$.

Q. I am sorry, you will have to explain that to me.

A. Now, what I am saying ---

Q. The relationship between what and what?

A. The relationship between the concentration of drug in the heart blood.

Q. Yes.

A. And the concentration of blood in the gutter.



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Q. Yes.

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A. Now, that one abnormality, that one spurious observation, I will use that term, I know that is not legally appropriate but I say it from my statistical analysis or viewpoint or from that of an investigator carrying out an experiment when confronted with these data I can't understand frankly how any of the consultants without subjecting this even to the most casual statistical analysis were able to reject these data out of hand.

These data to me strongly indicate that when the blood is obtained from an individual even after two or three hours following the post mortem, that is in the Gutter 2 samples, there is a very strong correlation between that sample and the post mortem cardiac blood sample. Therefore, I feel it is very easy to place confidence in this Estrella sample, assuming of course that it was obtained in the same or similar manner as the Gutter 2 blood in this study.

Q. Goodness knows I am no statistician, Dr. Mirkin, but I understand you to be saying that notwithstanding an incidence of once in, what is it, 25 samples here, there was the anomaly statistically the chances of that anomaly occurring



FF. 4

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2 are far less than 1 in 25. Is that what you're
3 suggesting?

4 A. Yes. Well, you see, I am saying
5 that the probability - yes, okay, I am saying that.

Q. Okay.

A. Okay, that is correct.

Q. And are you also saying that
8 statistically the chances of such anomalies occurring
9 are sufficiently small that your ability to rely upon
10 the correlation which exists in the other data is
11 not shaken. Your ability to rely upon the correlation
12 that is shown in the other data and therefore to
13 treat as reliable the Estrella sample is not
seriously shaken by the anomaly?

11 A. You know, I don't understand
15 what you mean by the other data, that is what I am
16 missing.

17 Q. I am talking about the other 23
18 or 24 cases.

10 A. Oh, yes.

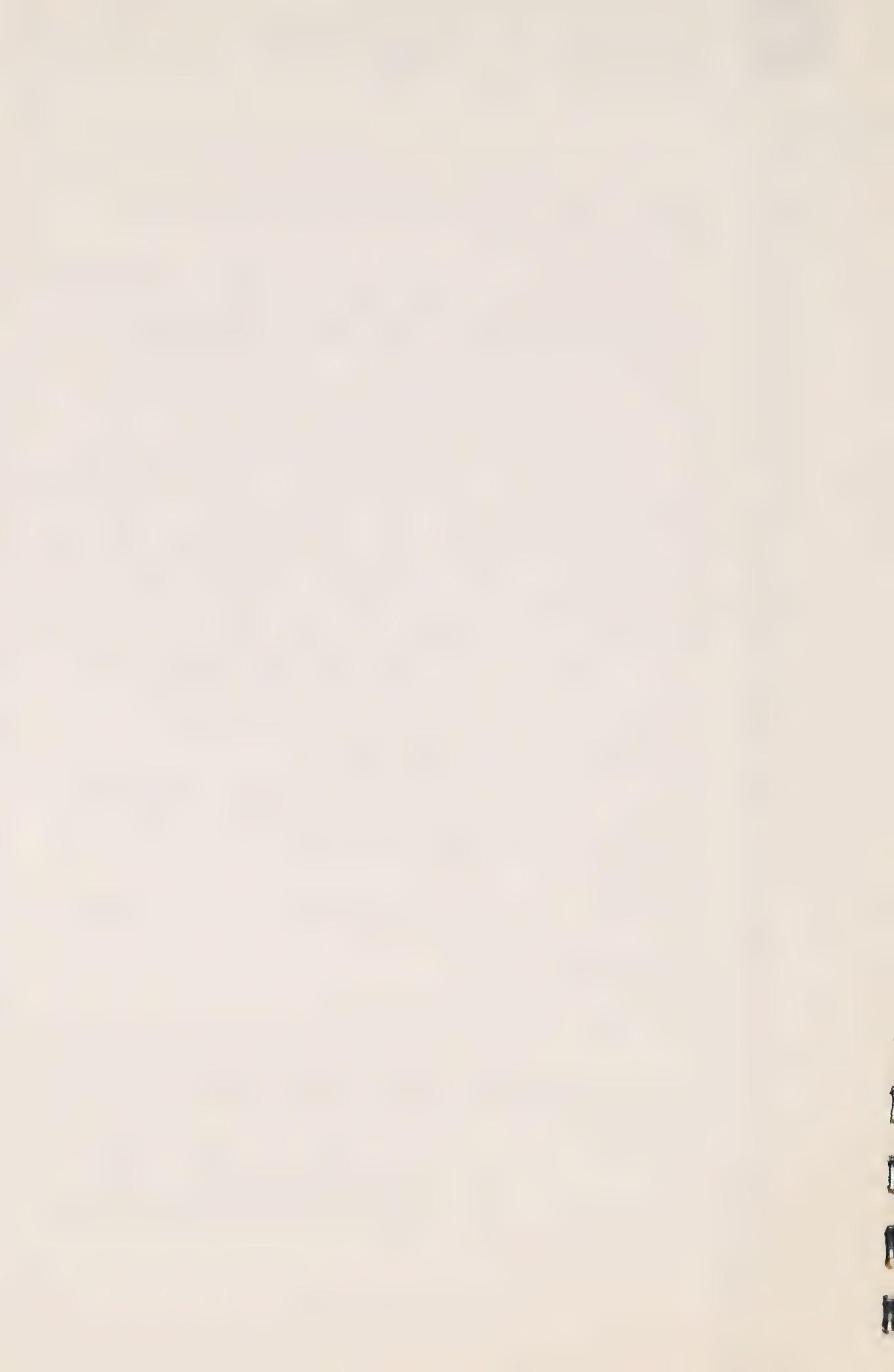
Q. Where you have told me there is
a good correlation between gutter blood and heart
blood.

A. Yes, that is correct then.

23 Q And the statistical probability

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2 of the anomaly occurring is sufficiently small that
3 it is your opinion you can rely with confidence upon
4 gutter blood concentrations?

5 A. Yes, on the presumption that
6 this is a valid experiment and replicates the
7 patient's sampling procedure.

8 Q. A question if I may please about
9 the Woodcock child. It had seemed to me that when
10 you were giving your evidence both in chief and in a
11 very large part in cross-examination you stressed
12 repeatedly with respect to Woodcock that it was an
13 important element in your assessment that that child
14 very likely had digoxin involvement in her death,
15 that digoxin had not been prescribed for her. Do you
16 recall saying that on a number of occasions over the
17 last couple of days?

18 A. Yes.

19 Q. It has been pointed out to you
20 today that at the referring hospital, at the Oshawa
21 General Hospital, she had indeed received digoxin.
22 Indeed, the amount she received is set out in the
23 chart if you need to look at them. Clearly she had
24 not received digoxin in the last four days of her
25 life which she spent at The Hospital for Sick Children.
Does the fact that the child had received digoxin at



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2 any stage of her life, that is to say at the
3 referring hospital, affect in any way the opinion
4 that you have expressed as to the likelihood or the
5 possibility of digoxin involvement in her death?

6 A. No, I think we would come up
7 with the same conclusions.

8 Q. All right. Do I take it there-
9 fore that you were focussing upon the last days of
10 her life as disclosed in The Hospital for Sick
Children treatment record?

11 A. That is correct.

(2)

12 Q. All right. May I move to the
13 extremely high serum concentration that was recorded
14 in the sample of what is to be believed serum from
15 the Inwood baby.

16 In cross-examination this morning my
17 friend Ms. McIntyre was asking you about the effects
18 upon that sample and therefore upon the concentration
19 measured in it of its rather dubious history. In
20 particular, she was asking you about the possibility
21 of evaporation of the sample in a refrigerator and
22 you conceded I think it was possible there could
23 have been some evaporation. Now, Doctor, you have
24 told us that the serum sample of 491 nanograms per
25 millilitre which was pointed out to you in the



FF. 7

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2 course of your evidence, you regard as a very
3 important piece of evidence in coming to the
4 conclusion that you have expressed about this child.

5 Ms. McIntyre suggested to you that
6 if perhaps the volume of the sample had been reduced
7 by 50 per cent as a result of evaporation that I take
8 it would have led to a false concentration by a
factor of 2 in the sample that remained?

9

A. Correct.

10

Q. Would you have regarded the
evidence as any less significant if the true
concentration had been 250 nanograms per millilitre?

12

A. Still in the toxic range and
one of very high risk to the patient.

14

Q. Or indeed if 75 per cent of the
sample had disappeared and the true concentration
in the entire sample had been 125 nanograms per
millilitre, would you still have regarded it as
important evidence upon which to base the same
conclusion you have expressed?

19

A. Yes.

20

Q. Thank you. Just one other
matter if I may, Doctor, for my understanding.

22

My friend Mr. Olah was talking to you
about the death of the child Pacsai and he was

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2 asking you to estimate if you could the earliest
3 possible time at which an overdose of digoxin might
4 have beed administered to that child so as to
5 produce the first signs of digoxin toxicity which you
6 and he discussed from the chart. He was talking to
7 you in the context of one adult vial of digoxin as
8 being the presumed size of the dose. He asked you
9 whether, if the dose were indeed a multiple vial
10 dose, by which he meant two or more vials, would one
11 expect to see an earlier onset of symptoms. Your
12 answer to him, as I recall it, was, yes, the larger
13 the dose the sooner you might reasonably expect to
14 see symptoms. My question is this, Dr. Mirkin. If
15 you are talking in terms of a presumed dose of one
16 adult vial I take it that is already a very substantial
17 overdose for an infant?

18

A. Yes, if the entire vial is
given, correct. We are talking about 500 micrograms,
is that correct?

19

Q. Yes.

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A. I think it is 250, yes, cc's.

21

Q. Is that not a sufficiently huge
overdose in the first place?

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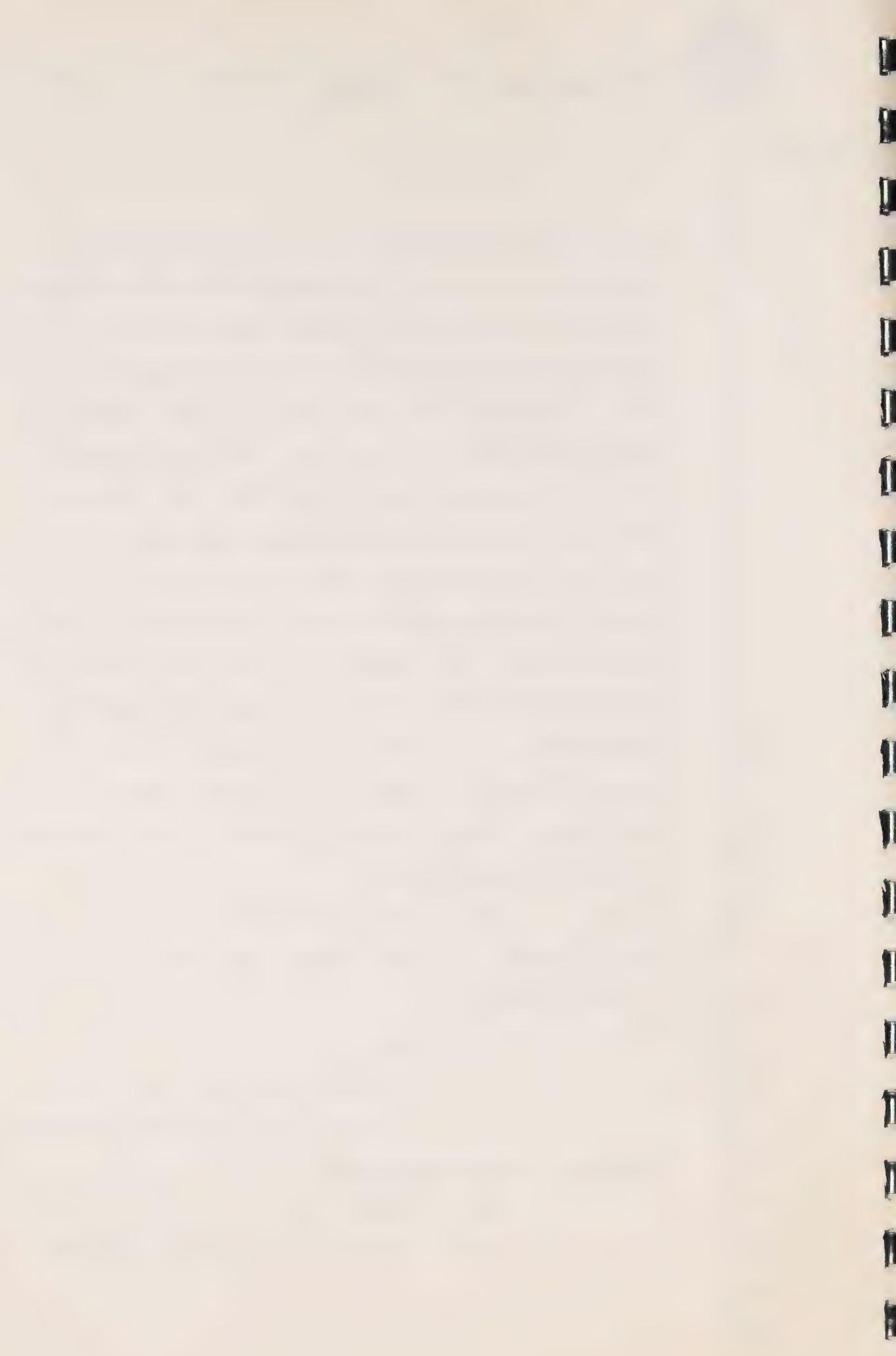
A. Yes.

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Q. That an increase in that dose

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2 would not produce the first effects of intoxication
3 at any appreciable earlier point in time?

4 A That's a difficult question to
5 answer but let me try.

6 Q I didn't want to end on an
7 easy one.

8 A Can I go to the Board for a
9 second and have three or four minutes?

10 Q Sure.

11 A I might as well finish this with
12 a flourish.

13 Q Don't strangle yourself on your
14 microphone now.

15 A As you have probably had drawn
16 before you there is a sort of a biological response
17 of most organs in the body to increase in concentration
18 of a given chemical or drug.

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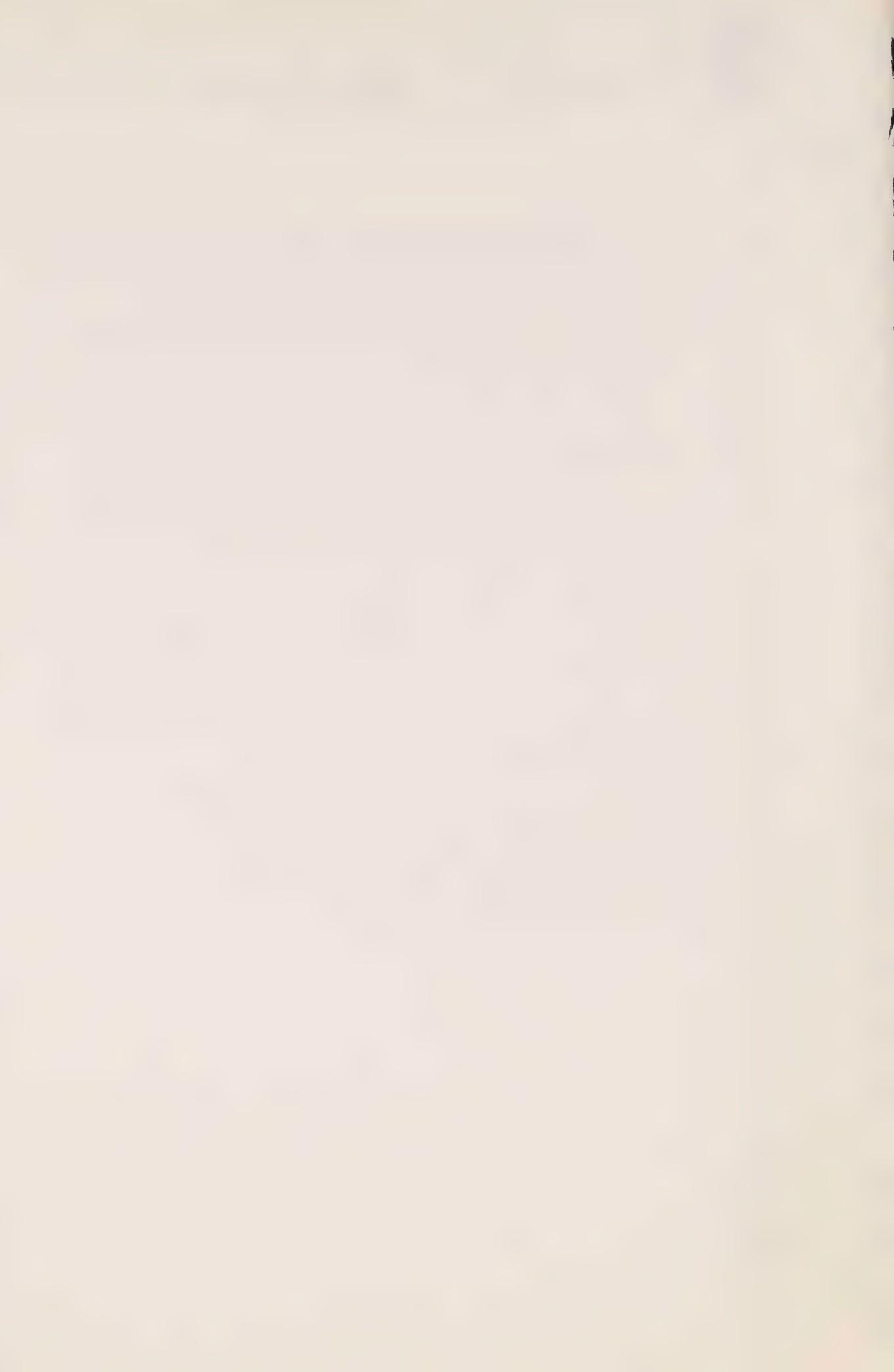
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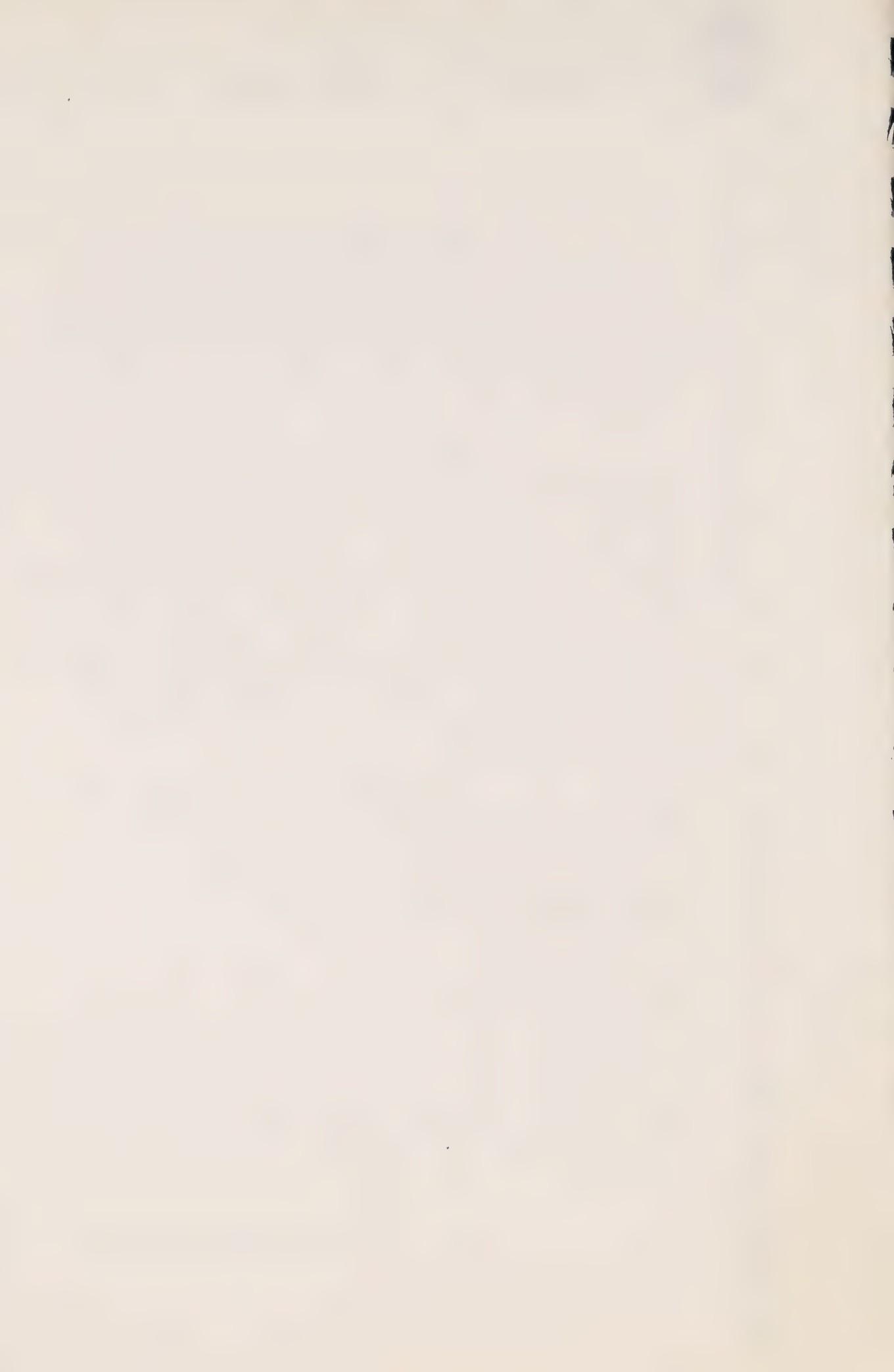
The response here I will put on
the abscissae. This could be blood pressure. Let
us say, in this case, it is contraction of the heart.
Here we have a dose - or it could be the concentration
of blood level in the body.

Under normal conditions, as we
go from zero, let us say, to infinity, or let us
give this a number - 100 - we get an increasing
response. So as we increase from 0 to 5 to 10 to 20,
the response increases. There is a point at which
the system can no longer elicit an increased response,
so-called plateau. This is a normal biological
response we all have.

In response to the question just
raised, if the initial quantity of drug given in
the presumed manner; that is, this entire vial of
adult strength digoxin is put into the patient, let
us assume we have achieved this concentration.
Therefore, we would have had a maximum response of
100 per cent. Okay? If we gave double that amount,
we would have been on this plateau of the curve. We
could not have enhanced this response further. That
is one answer to your question.

Q. Yes.

A. Let us suppose that this,





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2 which we are calling A, and this, which we are
3 calling B, this amount of drug produces a level
4 that was in here on this part of the dose response
5 curve. Now, here we have a response which is
6 roughly 50 per cent. This is A again. When I
7 give B, I produce this concentration. So, therefore,
8 I am still able to elicit a greater response from
the heart.

9 Now, this response could be
10 intoxication, it could be a positive response,
11 et cetera. So that is the difficulty I have in
12 answering the question. So I would say that if the
13 amount given the first time had not produced the
14 maximum capable response elicitable - is that a
15 word - by that tissue, then to give twice the
16 amount would have produced an increment in that
17 reaction. So we would have had a shorter time frame
for the onset of toxicity.

18 But your question raises the
19 possibility - and I think the reality that giving
20 500 micrograms; that is, 2 cc. of the adult dose,
21 would have been of such a magnitude as to produce
22 a maximum toxic effect. I think that is probably not
23 an unreasonable conclusion to reach. And I say
then, in response to the question, that giving twice

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GG3 2 that amount might not have shortened the onset of
3 the toxic effect.

4 Is that sufficiently clear?

5 THE COMMISSIONER: I thought it might
6 have shortened the onset but might not have made the
7 effect any greater.

8 MR. LAMEK: We are talking here
9 about the onset of the initial indications of
intoxication, sir.

10 THE COMMISSIONER: I see. I had
11 forgotten that that was what the question was about.

12 MR. LAMEK: Q. I take it, Dr.
13 Mirkin, no matter how quickly the onset comes on,
14 it is a subsequent stage of intoxication distribution
15 and, therefore, intoxication that is going to produce
16 the maximum effect, whether that be death or something
short of death?

17 We are looking at the onset of
18 initial symptoms, are we not?

19 A. Most people would probably
20 feel that the onset would be relatively fixed in
21 its nature, and I think it is a little different from
22 what I think I said in response to your question --
23 no, the gentleman behind you - I am looking over
you, excuse me.

24

25



1
GG4 2 MS. THOMSON: It is done frequently.
3 THE WITNESS: No, no. No.
4 MR. LAMEK: I am going to leave you
5 with that one, doctor.
6

7 THE WITNESS: Thank you very much.
8 MR. LAMEK: Thank you very much,
9 doctor. You can now go back to warm, mellow
10 Minneapolis!

11 THE COMMISSIONER: Thank you indeed,
12 doctor.

13 That is it as far as we are concerned.
14 I want Mr. Lamek to say something
15 about the schedule, but I will say initially that
16 we will not be sitting tomorrow for one, and I will
17 not be sitting on Monday. Some of you may be
18 involved in some other place, and Mr. Lamek will
19 decide unilaterally whether we will sit on Tuesday
20 or not.

21 MR. LAMEK: What I suggest, Mr.
22 Commissioner, is, if the Divisional Court matters
23 go over at all until Tuesday, that we not sit here
until Wednesday.

24 THE COMMISSIONER: All right. But
25 suppose it just goes over for judgment or something
like that, would you take the same position?



GG5

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2 MR. LAMEK: I am inclined to think
3 so, honestly.

4 THE COMMISSIONER: All right. You
5 seem to be determined to give me a holiday on
6 Tuesday as well.

7 MR. LAMEK: I am not determined; I am
8 merely suggesting it. But, of course, if we
9 complete the matter entirely on Monday, then we
10 would sit here on Tuesday and I propose next week
11 that we hear the evidence of Miss Costello, who is
12 one of the Head Nurses on Ward 4B and, the following
week, we have that Atlanta report.

13 THE COMMISSIONER: Has there been
14 any decision on the question of Miss Browne?

15 MR. LAMEK: That was the other
16 matter.

17 The statement has not at last been
18 distributed to all counsel. I don't know whether all
19 counsel have had an opportunity to consider whether
20 they need to cross-examine Miss Browne on that
21 statement. I would be very grateful to know because
22 next week would be a good time to fit that in as well.

23 Perhaps I could ask all counsel to
24 call me tomorrow if they do want to examine Miss
25 Browne. If I have not heard by mid-afternoon, I will



GG6

1

2 assume that people do not.

3

THE COMMISSIONER: All right.

4

Is that word to the wise sufficient?

5

All right, then, sine die.

6

7 ---- whereupon the hearing was adjourned at 4:15 p.m.
sine die.

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